Volume III of III (Pages A-17104 through A-26927)

04-1323, -1487

United States Court of Appeals For the Federal Circuit

ARTHROCARE CORPORATION,

Plaintiff/Counterclaim Defendant-Appellee,

and

ETHICON, INC.,

Counterclaim Defendant-Appellee,

ν

SMITH & NEPHEW, INC.,

Defendant/Counterclaimant-Appellant.

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE IN 01-CV-504, CHIEF JUDGE SUE L. ROBINSON

NON-CONFIDENTIAL JOINT APPENDIX

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December 21, 2004

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CONFIDENTIAL MATERIAL OMITTED FROM THE NON-CONFIDENTIAL JOINT APPENDIX

The material omitted from the Non-Confidential Joint Appendix relates to confidential agreements executed by ArthroCare Corporation, documents filed under seal with the district court, and Smith & Nephew, Inc.'s counterclaim, the dissemination of which the district court has restricted.

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IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

ARTHROCARE CORPORATION,

Plaintiff,

C.A. No. 01-504-SLR

SMITH & NEPHEW, INC.

Defendant.

SMITH & NEPHEW, INC.,

Counterclaim Plaintiff,

ARTHROCARE CORPORATION, AND ETHICON, INC.,

Counterclaim Defendants.

DEFENDANT SMITH & NEPHEW'S RENEWAL OF MOTION FOR JUDGMENT AS A MATTER OF LAW PURSUANT TO FED. R. CIV. P. 50(b)

Defendant Smith & Nephew, Inc. ("Smith & Nephew") renews its motion for judgment as a matter of law pursuant to Fed. R. Civ. P. 59(b). In support of this motion, Smith & Nephew has filed a memorandum and a declaration simultaneously herewith.

Dated: June 30, 2003

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IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

C.A. No. 01-504-SLR
ed Smith & Nephew's Rule 50(b) Motion for
nuse having been shown therefore, day of, 2003 that:

UNITED STATES DISTRICT JUDGE

CERTIFICATE OF SERVICE

I hereby certify that on this 30th day of June, 2003, a true and correct copy of the Defendant Smith & Nephew's Renewal Of Motion For Judgment As A Matter Of Law Pursuant To Fed. R. Civ. P. 50(b) was caused to be served on the attorneys of record at the following addresses as indicated:

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IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

ARTHROCARE CORPORATION,

Plaintiff,

SMITH & NEPHEW, INC.

Desendant.

C.A. No. 01-504-SLR

SMITH & NEPHEW'S OPENING BRIEF IN SUPPORT OF ITS RULE 50(b) MOTION FOR JUDGMENT AS A MATTER OF LAW

Dated: June 30, 2003

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I. NATURE AND STAGE OF THE PROCEEDINGS

For the Nature and Stage of the Proceedings, please see Smith & Nephew's Opening Brief in Support of Its Motion for a New Trial, filed concurrently.

II. SUMMARY OF THE ARGUMENT

ArthroCare failed to introduce evidence to show that Smith & Nephew itself directly infringes, contributes to the infringement by others, or actively induces infringement by others of any of the claims in suit. Since ArthroCare bears the burden of proving each of these allegations, its failure to carry these burdens requires judgment as a matter of law (JMOL) for Smith & Nephew on the following issues:

- (1) Neither Smith & Nephew's accused probes nor the use of these probes infiringe the patents-in-suit under the doctrine of equivalents.
- (2) Smith & Nephew does not directly infringe the method claims of the '592 and '882 Patents.
- (3) Smith & Nephew's accused probes do not infringe the claims of the '536 patent because ArthroCare failed to prove these probes include all of the elements required by the '536 patent within an "electrosurgical system" as required by the claims.
- because ArthroCare failed to prove that the accused probes satisfy the requirement that "the return electrode is not in contact with the body structure" or the requirement of "spacing a return electrode away from the body structure". Similarly, Smith & Nephew's accused probes do not infringe claim 47 of the '536 patent because ArthroCare failed to prove the return electrodes on the probes are "sufficiently spaced from the electrode terminal to minimize direct contact between the return electrode and the patient's tissue".
- (5) Smith & Nephew's accused probes do not infringe the claims of the '882 patent because ArthroCare failed to prove that the accused probes have "an electrode terminal," "a return electrode," "an active electrode," and "an electrically conducting terminal," all of which are required because the Certificate of Correction is not valid.

- (6) Non-suction models of Smith & Nephew's Saphyre products do not infringe claim 54 of the '882 patent because they do not "evacuat[e] fluid generated at the target site with a suction lumen having a distal end adjacent the electrode terminal".
- (7) Smith & Nephew is not liable for contributing to the infringement of any claim of the patents-in-suit.
- (8) Smith & Nephew is not liable for inducement of infringement of any claim of the patents-in-suit.

Moreover, no reasonable jury could find that Smith & Nephew did not prove—with clear and convincing evidence—that each of the asserted claims is invalid as anticipated and/or non-enabled. Entry of JMOL is therefore appropriate. Specifically:

- (9) ArthroCare presented no expert testimony or any other evidence to rebut Smith & Nephew's evidence that six prior art references anticipate the asserted claims. Nor did ArthroCare dispute the prior art status of any of Smith & Nephew's invalidating art.
- exclusively on an incomplete and cursory cross-examination of Smith & Nephew's expert, Dr.

 Taylor. Because this cross-examination fell far short of establishing any basis on which a reasonable jury could have found for ArthroCare on validity, Smith & Nephew is entitled to judgment as a matter of law. ArthroCare merely threw up a smoke screen of alleged "concessions by Dr. Taylor," and succeeded in confusing the jury. This confusion is highlighted best by the Pao '499 patent, which Smith & Nephew showed anticipated claims 46 and 56 of the '536 patent. ArthroCare's cross-examination on this point was limited to an element present only in claim 47, against which Pao was not even asserted. Nonetheless, the jury—apparently confused by ArthroCare's misleading cross-examination and argument—found Pao did not anticipate claims 46 and 56.
- (11) Likewise, ArthroCare presented no evidence to rebut Smith & Nephew's clear and convincing evidence that the '882 patent is invalid for lack of enablement. ArthroCare

ArthroCare must, because otherwise the '882 patent merely describes well-known electrosurgical techniques from the prior art). But despite saying that this "coblation" phenomenon is highly dependent on very exact parameters, the specification does not describe those parameters with specificity. Thus, to the extent that the '882 is not invalid as being anticipated by the prior art, it is invalid for lack of enablement.

III. CONCISE STATEMENT OF FACTS

The facts related to each of the grounds upon which Smith & Nephew moves for judgment as a matter of law are addressed in each of the corresponding sections of the argument.

IV. ARGUMENT

A. Applicable Legal Standards

Entry of judgment as a matter of law (JMOL) is appropriate where "the jury's findings, presumed or express, are not supported by substantial evidence or, if they were, that the legal conclusion(s) implied [by] the jury's verdict cannot in law be supported by those findings."

Pannu v. Iolab Corp., 155 F.3d 1344, 1348 (Fed. Cir. 1998). The question is not whether there is "literally no evidence" supporting the non-moving party, Lifescan, Inc. v. Home Diagnostics, Inc., 103 F. Supp. 2d 345, 350-51 (D. Del. 2000), but whether the evidence reasonably supports the jury's verdict. Gomez v. Alleghany Health Servs. Inc., 71 F.3d 1079, 1083 (3d Cir. 1995).

District courts grant JMOL if, upon the record before the jury, reasonable jurors could not have reached that verdict. Fed. R. Civ. P. 50; Perkin-Elmer Corp. v. Computervision Corp., 732 F.2d 888, 893 (Fed. Cir. 1984). In deciding whether to grant JMOL on any issue after a jury has returned a verdict, the court determines whether substantial evidence exists in the record to support the jury's verdict when the correct legal standard is applied. Markman v. Westview Instruments, Inc., 52 F.3d 967, 975 (Fed.

¹ In addition to the specific grounds of IMOL discussed in detail herein, Smith & Nephew also renews and reserves all of its arguments with respect to claim construction as set forth in its claim

Cir. 1995), aff'd, 517 U.S. 370 (1996). Substantial evidence is the quantum of evidence that reasonable jurors would accept as adequate to support the finding under review.

Perkin-Elmer, 732 F.3d at 893.

JMOL should be granted if "a party has been fully heard on an issue and there is no legally sufficient evidentiary basis for a reasonable jury to find for that party on that issue." Fed. R. Civ. P. 50(a); see Northview Motors, Inc. v. Chrysler Motors Corp., 227 F.3d 78, 88 (3rd Cir. 2000). In a patent infringement action, "JMOL of non-infringement is properly granted if no reasonable jury could have concluded that a limitation recited in the properly construed claims is found in the accused device, either literally or under the doctrine of equivalents." Medironic. Inc. v. Advanced Cardiovascular Systems, Inc., 248 F.3d 1303, 1309 (Fed. Cir. 2001).

To overcome a motion for JMOL, the non-moving party must point to "substantial evidence" to support a finding in its favor. See Malta v. Schulmerich Carillons, Inc., 952 F.2d 1320, 1329 (Fed. Cir. 1991). Merely "offhand and conclusory statements" are not sufficient to overcome the motion. Id. at 1327.

The patent owner bears the burden of proving infringement (by a preponderance of the evidence) that the accused device, or use of that device, has all the limitations of the asserted claims. Novartis Corp. v. Ben Venue Labs., Inc. 271 F.3d 1043, 1046 (Fed. Cir. 2001).

B. Smith & Nephew's Accused Probes And The Use Of These Probes Do Not Infringe The Patents In Suit Under The Doctrine Of Equivalents

ArthroCare introduced no evidence of infringement under the doctrine of equivalents, and JMOL on this issue should be granted. ArthroCare attempted to introduce evidence regarding equivalent infringement for the first time during redirect examination of its expert Dr. Goldberg. The Court properly excluded this belated "rebuttal" evidence. (D.L 415 at 1144). In making the ruling, the Court stated that ArthroCare should have brought the matter up during direct examination and that, even if it had, the testimony would not have been permitted because the equivalence analysis in Dr. Goldberg's report was insufficient. (Id.). Thus, judgment as a

construction brief (D.I. 246 and 282), to the extent that the Court adopted a different claim construction from that set forth by Smith & Nephew.

matter of law that Smith & Nephew does not infringe any claim of any patent-in-suit under the doctrine of equivalents should be granted.

C. Smith & Nephew Does Not Directly Infringe The Method Claims Of The '592 And '882 Patents

ArthroCare failed to provide any evidence that Smith & Nephew itself uses or has used the Saphyre, ElectroBlade, or Control RF probes in surgery as required by the claims of the '592 and '882 method patents. "A method claim is directly infringed only by one practicing the patented method." Joy Technologies, Inc. v. Flakt, Inc., 6 F.3d 770, 775 (Fed. Cir. 1993) (emphasis added). ArthroCare has offered no evidence from which a reasonable jury could conclude that Smith & Nephew uses its Saphyre, ElectroBlade, or Control RF probes to perform each step of the methods covered by ArthroCare's claims. Indeed, the only evidence at trial was that Smith & Nephew does not use the accused probes. (See, e.g., D.L 414 at 961). Thus, the Court should enter judgment as a matter of law that Smith & Nephew does not directly infringe any claim of the '882 or '592 patent.

D. The '536 Patent

 JMOL Of Non-Infringement Of The Claims Of The '536 Patent Is Appropriate Because ArthroCare Failed To Prove That These Probes Are Used As Part Of The "Electrosurgical System"

Claim 45 of the '536 patent, and the claims that depend from it (asserted claims 46, 47, and 56) claim an electrosurgical system, which includes its own fluid supply. Specifically, the '536 patent is directed to an electrosurgical system that can be used in open surgery — e.g.. surgery in a dry environment — because "[e]lectrically conductive liquid, such as isotonic saline, is directed through a fluid path past a return electrode and to the target site to generate a current flow path." (JTX-1, col. 3, lines 26-30). As described in the Summary of the Invention:²

The above described method is particularly effective in a dry environment (i.e., the tissue is not submerged in fluid), such as open, laparoscopic or oral surgery, because the electrically conducting liquid provides a suitable current flow path from the target site to the return electrode.

² The Summary of the Invention is an optional part of the patent application. "Such summary should, when set forth, be comensurate with the invention as claimed..." 37 C.F.R. §1.73.

(Id. at col. 3, lines 37-41). This is distinct from arthroscopic surgery, in which the joint is filled with saline (which is a biocompatible fluid) in order to move the soft tissue out of the way of the surgeon and wash out debris that is produced during the operation. Such a supply of saline in arthroscopic surgery is completely separate from any electrosurgical instrument, and the saline is typically supplied by either an IV bag or a separate system such as the Intelliger.

The Court construed the term "system" in claim 45 of the '536 patent to mean "an assemblage or combination of things or parts forming a unitary whole." (D.I. 354). The claims require that the system include several elements, including "an electrically conducting fluid supply for directing fluid to the target site, "which thus must all be part of the "unitary whole." However, ArthroCare's expert ignored the Court's construction and the requirement that an electrically conducting fluid supply for directing fluid to the target site be part of the claimed system — i.e., as part of: 'unitary whole"—such that the system could be used in open surgery.

Dr. Goldberg testified:

- Q. Now, is the Saphyre bipolar ablation probe used as part of an electrosurgical system?
 - A. Yes, sir, it is.
- Q. Now, is the electrically conductive fluid supply physically connected to this probe that we've been looking at?
 - A. Not this probe, sir.
- Q. So how is it then that this probe is part of a system that includes electrically conductive fluid?
- A. Again, my understanding of a system is that things don't have to be physically in contact. Another example that just came to mind is when we have a wireless computer system or an audio system, the mouse doesn't have to be connected by a wire to the computer to be part of the same system. They're all functioning to put in the data or to listen to the stereo. So it doesn't have to be part of, physically connected. The electrical fluid in the joint will get there. The surgeon has to fill the entire joint to distend it and the fluid will get there. It's all part of the system, sir.

(D.I. 411 at 398-399) (emphasis added).

In his testimony, Dr. Goldberg clearly failed to apply the Court's construction of the term "system." He never described how the Saphyre and a separate fluid supply form an "assemblage or combination of things or parts forming a unitary whole." Instead, he actually disavowed and disagreed with the Court's claim construction, and said that "it doesn't have to be part of, physically connected." (Id.). Since he did not agree with the Court's claim construction, he obviously did not provide any evidence that was in accordance with the Court's claim construction. Instead, all he said was that "the fluid will get there." (Id.). But he didn't say how.

These omissions became even more apparent during Dr. Goldberg's testimony regarding the individual claim elements. For each of the accused products, Dr. Goldberg testified that the product comprises the first two elements of the system required by claim 45. However, Dr. Goldberg's analysis ignored the third element of the system, the electrically conducting fluid supply. For the Saphyre, Dr. Goldberg testified:

And there is electrically conducting fluid supplied because this is arthroscopy and there is electrically conductive fluid delivered by the surgeon and the people in the operating room to the joint.

(D.I. 411 at 447). This testimony is very misleading because Dr. Goldberg, and ArthroCare continually focused on arthroscopic surgery. But the claims are not so limited. In fact, if one were to use the Saphyre in, for example, an oral surgery such as described in the Summary of the Invention of the '536 patent' the device would not work because the Saphyre does not have a fluid supply as part of its system. Dr. Goldberg actually recognized this in his experimentation with the Saphyre product (Id. at 416):

Q. You mentioned that you also tested the Saphyre when the return electrode was in air and the active electrode was in saline; is that right?

A. Yes, sir.

Q. Can you describe for the jury what happened when you used the Saphyre probe in that mode?

³ Likewise, for the Control RF and ElectroBlade products, Dr. Goldberg failed to provide any evidence that the products are a "system" as required by Claim 45.

A. It didn't work. Thus, any testimony that the Saphyre probe includes the fluid supply simply because it is designed for arthroscopic surgery is misleading and incorrect.

For the Control RF, Dr. Goldberg did not even mention a fluid supply and simply said (Id. at 448):

There is electrically conductive fluid, as well as a current flow path when the generator is on.

Similarly, for the ElectroBlade, instead of describing a fluid supply (Tr. at 449):

Up the shaft is a return electrode. It's connected to the generator and it's in electrically conductive fluid and there is a current flow path through the electrically conductive fluid at the time the generator was activated.

While the Smith & Nephew probes are used in the presence of saline or other electrically conducting fluids, that fluid is not supplied to the target site by the probes. (D.I. 415 at 976 and 1013). Fluid, typically from an IV bag, is instead introduced by a separate and distinct piece of medical equipment such as the cannula that is also used for the videoarthroscope. (D.I. 414 at 815-16; D.I. 268, Ex. 43). That separate piece of equipment is not part of the "electrosurgical system." The Smith & Nephew probes and fluid supply are not part of the same assemblage or combination of things or parts forming a "unitary whole."

Moreover, ArthroCare introduced no evidence that the alleged system included a fluid supply "for directing fluid to the target site." Instead, the testimony was uncontroverted that the purpose of the fluid supply used with the Smith & Nephew probes was instead to flood the inside of the joint in order to move soft tissue back and also to wash out debris. (D.L 414 at 780-81 and 790)

With respect to ArthroCare's attempt to argue that the separate Smith & Nephew Intellijet fluid supply system was part of an "electrosurgical system," that evidence was limited to the "System Configuration" contained in the ElectroBlade IFU. (D.I. 411 at 497; PX 189). However, Karen Drucker testified that this System Configuration is for compliance with European regulations. Thus, to the extent this evidence is taken to support the inference that the ElectroBlade and the Intellijet, used in this configuration, are an "electrosurgical system," it is only evidence for their use in Europe. Moreover, Ms. Drucker explained that IFU showed that the Intellijet system was not completely separate from the ElectroBlade system. (D.I. 415 at 1018).

Since the probes each lack the fluid supply element as part of the electrosurgical system as required by the claims, they cannot directly infringe these claims. See KCJ Corp. v. Kinetic Concepts. Inc., 223 F.3d 1351, 1358-59 (Fed. Cir. 2000); Laitram Corp. v. Rexnord, Inc., 939 F.2d 1533, 1535 (Fed. Cir. 1991) ("To establish infringement, every limitation set forth in a patent claim must be found in an accused product or process exactly or by substantial equivalent."). Because ArthroCare failed to present evidence by which a reasonable jury could find that any of the accused products satisfies the "system" requirement of claim 45 that is incorporated into asserted claims 46, 47, and 56, JMOL of non-infringement of these claims is proper.

E. The '592 Patent

1. Smith & Nephew's Accused Probes Do Not Infringe The Claims Of The '592 Patent Because ArthroCare Has Failed To Prove That The Accused Probes Satisfy The Requirement That "The Return Electrode Is Not In Contact With The Body Structure" Or The Requirement Of "Spacing A Return Electrode Away From The Body Structure"

Claim 1 of the '592 patent requires "positioning a return electrode ... such that [it] is not in contact with the body structure" and claim 23 requires "spacing a return electrode away from the body structure." The Court construed these terms to mean that "the return electrode is not to contact the body structure at all during the performance of the claimed method." (D.I. 353) (emphasis in original).

ArthroCare's expert, Dr. Goldberg, again ignored the Court's claim construction when he rendered his opinion that the Smith & Nephew probes infringe:

Q. Now, does that portion of the claim as construed by the Court require that the Saphyre bipolar ablation probe return electrode never contact the tissue during the course of an entire arthroscopic procedure?

A. No, it doesn't. Mr. Bobrow, you raised a very important -

⁶And, as discussed above, ArthroCare has completely failed to provide any evidence that a separate fluid supply is in any way equivalent to a unitary whole.

Claim 47 of the '536 patent includes a similar limitation which reads "the return electrode being sufficiently spaced from the electrode terminal to minimize direct contact between the return electrode and the patient's tissue." Thus, Smith & Nephew submits that ArthroCare failed to prove infringement of that claim for the same reasons.

A. I was about to try to explain to the members – the ladies and gentlemen of the jury as to why this is a very important point. The claim is talking about a method for applying electrical energy, so the issue is whether or not a device infringes when the electrical energy is not — when it is being applied. There are a lot of parts to a surgery, including putting in the camera, taking out the camera, taking care of the patient that don't involved applying electrical energy. So the key is, is this method being infringed when it's fulfilling the claim which is when the energy is being applied? So the only way not to infringe this claim with the device is to make sure that the return electrode—

is always in contact when the energy is on. And as the videotape and Mr. Marsden suggested, very clearly there is occasional contact frequently, but often there isn't. The probe is designed to enable they're not being contact. If it's not in contact, it's being infringed.

(D.L. 411 at 421-22) (emphasis added).

Dr. Goldberg's testimony that the use of Smith & Nephew's products infringe the claims of the '592 patent is based on ArthroCare's previously-rejected interpretation of the claim term, rather than the Court's construction. Specifically, by stating that the "only way not to infringe this claim with the device is to make sure that the return electrode ... is always in contact when the energy is on," Dr. Goldberg is appling ArthroCare's temporal limitation that the Court specifically rejected. (D.I. 352, p. 6) ("Both parties have proposed a claim construction that improperly imports a time limitation into the claim. The claim limitation in dispute has no relation to the time required to perform the method.").

The following chart demonstrates how Dr. Goldberg has ignored the Court's construction and continued to apply ArthroCare's original and now rejected construction:

ArthroCare's Rejected Argument	Dr. Goldberg's Testimony
"Smith & Nephew's proposed experts have not offered any evidence or opinion that the return electrode of the Sarbyre is always contacting	"the only way not to infringe this claim with the device is to make sure that the return electrode is always in contact when the energy is on." (Tr. at 421-22) (emphasis added).

Further the Court's claim construction refers to the performance of all three steps of the method. Only one of those steps requires the application of RF energy. However, Dr. Goldberg and ArthroCare completely ignored the first step of the method — "positioning the electrode

terminal into at least close proximity with the target site." (JTX-3, claims 1 and 23). Both ArothroCare and Dr. Goldberg ignored return electrode contact with the tissue when the probe is being positioned before the RF energy is being applied. This misleading view is evident when Dr. Goldberg states "when we're talking about activation of energy, which is what the claims are referring to, they're limiting it to two very small periods of time." (D.I. 415 at 1119) (emphasis added). But the Court's claim construction expressly rejected any time limit, and certainly is not limited to the time period of activation of energy. Thus, Dr. Goldberg's assertion of "what the claims are referring to" is simply incorrect.

In fact, ArthroCare introduced absolutely no evidence that the method of using the accused products met these limitations of the '592 patent under the Court's claim construction. Indeed, even all of its cross-examination of Smith & Nephew's witnesses was based upon the erroneous claim construction which ArthroCare had proposed, and which the Court had rejected. (See, e.g., D.I. 415 at 983 and 1035-36).

Instead, under the Court's claim construction, all of the evidence at trial showed that the return electrode frequently contacted tissue at various times when one or more of the three steps of the method was being practiced. As can be seen in the various sales-training videos (DTX 315, DTX 316, and DTX 897), the three steps of the method are continually being practiced — if the power is not being applied, the active electrode is being positioned for the next time that the surgeon applies the power. Thus, Dr. Goldberg's and ArthroCare's evidence was not based on the Court's claim construction and cannot support a verdict of infringement.

The confusion regarding the time period in which one analyzes the use of the accused devices was further compounded in ArthroCare's closing argument, in which Mr. Bobrow misleadingly argued:

ArthroCare attempted to mislead the jury when it twicestopped the Saphyre video at an instant in the middle of the performance of the claimed method when the return was not contacting tissue (D.L 415 at 985), and suggested this was proof of infringement. The Court's claim construction was clear: the return electrode is not to contact the body "at all" during performance of the method and the method is not complete until all three steps are performed.

There is no minimum time period. If energy is applied for three seconds and the return electrode is not in contact for those three seconds, and the active electrode is close to the tissue, and RF energy is applied and all the other language is met, this is satisfied. This is satisfied.

Now, if in the fourth second, it hits the tissue, well, then it's not practicing the method. But if in the fifth and sixth seconds, it's away from the tissue again, then it is. There is no time limitation.

I can perform this method for two seconds. I could perform it for two minutes. There is no time limitation.

(Tr. at 1580-81) (emphasis added). While this Court indeed held that there were no temporal limitations to the performance of the claimed method, it also held that that "the return electrode is not to contact the body at all during the performance of the claimed method." (4/9/03 Memorandum Order at 2, D.I. 353) (emphasis in original). Thus, if the energy was still on when the return electrode "hits the tissue" in the fourth second of Mr. Bobrow's example, there would be no infringement no matter what happened over the first three seconds.

Finally, ArthroCare presented no direct evidence that doctors do not touch the return electrode to tissue during use of the accused products. In fact, ArthroCare presented no evidence that the doctors who used the devices actually used them to perform the method of the asserted claims. Dr. Goldberg's only opinion, and all that the evidence showed, was that "doctors have used the Saphyre after the [patents' issue] date in the United States." (Tr. at 462; see also Tr. 465-66 and 470). There is not one shred of evidence that the uses described by Dr. Goldberg were actually directly infringing the methods of the '592 patent.

Dr. Goldberg ignored the Court's claim construction and presented its infringement case based on ArthroCare's long rejected argument of what the claim means. ArthroCare thus failed to present any relevant evidence by which a reasonable jury could find that the use of any of the three accused products satisfies the return electrode "not in contact" requirement. JMOL of non-infringement is proper.

F. The '882 Patent

 There Is No Infringement Of The '882 Patent Because The Certificate Of Correction Is Not Valid

The Certificate of Correction broadened the scope of claim 1 of the '882 patent by reducing the number of electrodes required by the claim. Prior to the Certificate of Correction, claim 1 of the '882 patent required four electrodes: an electrode terminal, an active electrode, a return electrode, and an electrically conducting terminal. (JTX-2 at col. 24 lines 8-12). After the Certificate of Correction, the claim required only two electrodes: an electrode terminal and a return electrode. (See Certificate of Correction attached to JTX-2).

It was undisputed at trial that if the Certificate of Correction had not been obtained—or was invalid— Smith & Nephew would not infringe the '882 patent, because the accused Control RF and Saphyre products have only two electrodes. (See testimony of ArthroCare's expert, Dr. Goldberg, (Tr. 1110) (D.I. 415)).*

As set forth in Smith & Nephew's brief in support of its motion for a new trial (filed concurrently), Smith & Nephew contends that the issue of validity of the Certificate of Correction should never have been submitted to the jury. However, since it was submitted to the jury, and there was no evidence supporting the jury's finding that the Certificate of Correction was valid, IMOL should be entered for Smith & Nephew on this issue.

The controlling case on the validity of the Certificate of Correction is Superior Fireplace v. Majestic Products, 270 F.3d 1358, 1368 (Fed. Cir. 2001). In that case, the Federal Circuit explained that corrections are permitted under 35 U.S.C. § 255 only in order to correct "a mistake of a clerical or typographical nature, or of minor character, which was not the fault" of the PTO. As explained in Superior Fireplace, a mistake "of a minor character" may not broaden the claim. 270 F.3d at 1376. Since the Court has already determined here that the Certificate of Correction broadened the claim (D.I. 417 at 1550-51), and ArthroCare's expert Dr. Goldberg admitted as

ArthroCare tried to create some confusion with the jury by having its expert, Dr. Goldberg. testify that the ElectroBlade product might be viewed as having more than two electrodes. (Tr. at 1111-13). However, this testimony was irrelevant and confusing, since the '882 patent had never

much (D.I. 415 at 1109-11), in order for the Certificate of Correction to be valid, the alleged "mistake" that was "corrected" must therefore qualify as one "of a clerical or typographical nature."

A Certificate of Correction can validly correct a clerical or typographical mistake only if a review of the file history reveals (1) there was indeed a "clerical or typographical mistake" and (2) it is both "manifest" that there is an error to be corrected and it is also "manifest" how to correct the error. 270 F.3d at 1370.

In Smith & Nephew's Opening Brief in Support of its Inequitable Conduct Case, Smith & Nephew showed how the Certificate of Correction at issue was actually obtained by ArthroCare's in-house attorney, John Raffle, in order to broaden the claim so that it could sue Ethicon — in other words, that there was no "mistake" involved at all. (D.I. 442 at 35). However, putting that issue aside, the prosecution history and the testimony from trial shows that no reasonable juror could have found that either the alleged mistake or the solution for correcting the alleged mistake was "manifest," for at least the following four reasons:

a. A Simultaneous Complementary Change to Claim 26 Shows That There Was No Manifest "Error" in Claim 1

Mr. Raffle filed the Request for Certificate of Correction on December 17, 1997. (DTX 306 at 234-35). In the Request for Certificate of Correction, Mr. Raffle represented that the alleged "errors" being corrected arose in connection with an amendment he filed during prosecution of the '882 patent application on March 25, 1997. (DTX 306 at 200-10). One of the alleged errors involved amending application claim 23 (which became patent claim 1) so that the claim required both an "active electrode" and an "electrode terminal." However, in that very same amendment, Mr. Raffle also amended application claim 52 (which became patent claim 26) so that it also required both an "active electrode" and an "electrode terminal." Thus, Mr. Raffle

even been asserted against the ElectroBlade product. (See, e.g., ; Tr. at 1214; see also D.I. 405 at 3).

Although the Request refers to claim "23," it is clear that this was a mistaken reference to the application claim number, and that the request sought to change claim 1. (DTX 306 at 239; D.I. 417 at 1510).

simultaneously amended the claims that would become claims 1 and 26 so that they both included an "active electrode," and an "electrode terminal," (as well as a "return electrode"). (See D.I. 417 at 1511-13):¹¹

Q. So just to review, in Claim 1, in the second — in the third line, you changed active electrode to electrode terminal; right?

A. Yes.

Q. And in the third line of Claim 26, you left active electrode all alone. You didn't change it; right?

A. That's correct.

Q. Okay. And then in the sixth line of Claim 1, you left active electrode again all alone, didn't change it; right?

A. Correct.

Q. And in the corresponding sixth line of Claim 26, you changed active electrode to electrode terminal; right?

A. Correct.

Thus, anyone reviewing the file history of the '882 patent would see that one instance of "active electrode" was changed to "electrode terminal" in both claims 1 and 26, whereas the other instance of "active electrode" in both claims 1 and 26 was left unchanged. Accordingly, no reasonable juror could find that it was "manifest" that the term "active electrode" was in error in claim 1, or that it was "manifest" that "active electrode" should be changed to "electrode terminal" in claim 1.

b. The Amendments To Claims 1 And 26 Created Inconsistent Antecedent Basis Problems – And There Was No Way Of Knowing Which Was Correct

ArthroCare has argued that an error in antecedent basis in claim 1 supports the notion that the so-called "mistake" was "manifest."

Generally, the first time an element is referred to in a claim, an indefinite article ("a" or "an") is used, whereas thereafter, a definite article ("the or "said") is used to show that the same

A side-by-side comparison of Mr. Raffle's amendments to application claims 23 and 52 (which became patent claims 1 and 26 respectively) was used to cross-examine Mr. Raffle at trial. (Exhibit A to accompanying Declaration of William J. Marsden, Jr.

claim element is being described. To use a definite article for the first mention of a claim term is sometimes referred to as improper "antecedent basis."

In this case, as a result of the amendment Mr. Raffle made to claim 1, the term "active electrode" did not have a proper antecedent basis. (JTX-2, col. 24, lines 5-12). However, anyone reviewing the file history would see that there were other instances in the claims of the '882 patent in which there was an improper antecedent basis. For example, as a result of the amendment Mr. Raffle made to claim 26, at the very same time as his amendment to claim 1, the term "electrode terminal" also did not have a proper antecedent basis. (JTX-2, col. 25, lines 24-30). Thus, anyone reviewing the file history for the '882 patent would see that (a) Mr. Raffle amended claim 1 to include both an "active electrode" and an "electrode terminal," but did not provide proper antecedent basis for the "active electrode," and (b) at the very same time, he amended claim 26 to include both an "active electrode" and an "electrode terminal," but did not provide proper antecedent basis for the "electrode terminal."

Given this, it would not be possible for one reviewing the file history to determine (1) whether any error occurred at all, or if so (2) whether the error was in claim 1 or 26 or both, or (3) whether "electrode terminal" should be "active electrode" or "active electrode" should be "electrode terminal." Certainly, no reasonable juror could possibly find that any of this was "manifest." If anything, to the extent an antecedent basis error would be recognized at all, the most obvious way to correct the error would be to simply change "the" to "an" to correct the antecedent basis.

e. ArthroCare's Failure To Object To The Examiner's
Statement Of Reasons For Allowance Shows That There Was
No "Manifest Error" In Claim 1

Further, anyone reviewing the file history would see that the Examiner had relied on the alleged "mistake" in claim 1 when deciding to issue the '882 patent, and would thus not think that the alleged error was "manifest."

As is not uncommon, the Examiner provided a statement of his reasons for allowing the '882 patent to issue, which relied on the scope of application claim 23 as of June 22, 1997 — i.e.,

before it was broadened by Mr. Raffle's Certificate of Correction (DTX 306 at 222) (emphasis added):

The following is an examiner's statement of reasons for allowance: The prior art of record does not disclose or suggest a method for applying energy to a target site on a patient body structure comprising providing an electrode terminal and a return electrode electrically coupled to a high frequency voltage source; positioning the active electrode in close proximity to the target site in the presence of an electrically conducting terminal; and, applying a high frequency voltage between the electrode terminal and the return electrode, the high frequency voltage being sufficient to vaporize the fluid in a thin layer over at least a portion of the electrode terminal and to induce the discharge of energy to the target site in contact with the vapor layer.

As can be seen, the Examiner's Reasons for Allowance was clearly based on the "uncorrected" scope of application claim 23 as it essentially quotes that claim (compare the Reasons for Allowance with application claim 23 as set forth in the Amendment of March 25, 1997, DTX 306 at 201).

Moreover, anyone reviewing the file history would know that such a statement of Reasons for Allowance is binding on the patentee, absent an objection by the patentee. See Elkay Mfg. Co. v. Ebco Mfg. Co., 192 F.3d 973, 979 (Fed. Cir. 1999) (holding that failure to respond to an examiner's reason for allowance functioned as a disavowal of a different interpretation of the claim). Thus, since ArthroCare never objected to the binding statement of Reasons for Allowance, there is simply no way that anyone reviewing the file history would think that it was "manifest" that there was an error in the statement, and thus in claim 1.

d. The Alleged Errors Were Not Even "Manifest" To Mr. Raffle

As shown above, claims 1 and 26 both included an "active electrode" as well as an "electrode terminal," and they both had antecedent basis problems. Mr. Raffle carefully reviewed both claims when the '882 patent issued. (DTX 306 at 235). Yet he only sought a Certificate of Correction with respect to claim 1, and he was perfectly happy to leave claim 26 alone (Tr. 1541) (D.L 417):

- Q. On the certificate of correction, you did not ask to change Claim 26; right?
 - A. I believe that's correct, yes. Claim 26.

- Q. As issued.
- A. As issued. That's correct.
- Q. You did not ask to correct that?
- A. That's correct.

Thus, to Mr. Raffle himself, the inclusion of both an "active electrode" and an "electrode terminal" in a claim was not a "manifest" error, and an antecedent basis problem with respect to one of those electrodes was also not a "manifest" error. Of course, as shown in Smith & Nephew's Opening Brief in Support of its Inequitable Conduct Case, Mr. Raffle's true motive in seeking the Certificate of Correction was to broaden claim 1 of the '882 patent for ArthroCare's lawsuit against Ethicon, and had nothing at all to do with correcting any actual "errors."

In light of this clear evidence, no reasonable juror could have found either the alleged errors in claim 1 of the '882 patent to be "manifest," or the manner of correcting those alleged errors to be "manifest." Accordingly, JMOL should be entered that the Certificate of Correction is not valid, and therefore that there is no infringement of the '882 patent by the accused Smith & Nephew products.

Non-suction Models of Smith & Nephew's Saphyre Products do Not Infringe Claim 54 of the '882 Patent Because ArthroCare Has Failed to Prove that these Products Satisfy the Requirement of "Evacuating Fluid Generated at the Target Site with a Suction Lumen Having a Distal End Adjacent the Electrode Terminal"

Claim 54 of the '882 patent requires evacuating fluid with a suction lumen having a distal end adjacent the electrode terminal. Several of the Saphyre models accused of infringing this claim do not come with suction. Thus, it is impossible for these models to evacuate fluid and infringe claim 54. ArthroCare has admitted that these products do not infringe this claim. D.I. 417 at 1493-94, D.I. 405 at 3. Thus, JMOL of non-infringement of claim 54 is appropriate with respect to these products.

G. Smith & Nephew Is Not Liable For Contributing To The Infringement Of
Any Claim Of The Patents-In-Suit

Even if ArthroCare had offered evidence of direct infringement by Smith & Nephew customers, ArthroCare has not presented sufficient evidence from which a reasonable jury could find Smith & Nephew liable for contributory infringement under 35 U.S.C. § 271(c). As part of its case-in-chief on contributory infringement, ArthroCare had to prove that Smith & Nephew's probes are not staple articles of commerce suitable for substantial non-infringing uses. See 35 U.S.C. § 271(c). The focus of the analysis of non-infringing uses is the thing actually sold by the accused infringer. Hodosh v. Block Drug Co., 833 F.2d.1575, 1578 (Fed. Cir. 1987). Yet ArthroCare never addressed the non-infringing uses, much less presented evidence that those uses are not substantial.

Indeed, Dr. Goldberg's only testimony on the contributory infringement or the noninfringing uses for Smith & Nephew's probes is:

- Q. Now, Dr. Goldberg, the last subject I have for you today has to do with contributory infringement. Have you formed an opinion about whether Smith & Nephew is contributing to the infringement of ArthroCare's asserted claims through its sale of the Saphyre, the Control RF and the ElectroBlade?
 - A. Yes, I have.
 - Q. Tell us your opinion, please?
- A. Smith & Nephew, by the fact that they are selling this device, teaching folks how to use it in an infringing way, are certainly contributing to the infringement of these patents.
- Q. And can you tell us of any documents or other information on which you base your opinion?
- A. Well, all the documents we have just gone through, the instructions for use and the sales guides, are clearly pointing, they are teaching to, and providing product to infringe these patents. And an important point to add, in terms of the contributing to infringement, is that, as I have shown, the documents themselves say that they are selling these devices to be used for arthroscopic surgery, not for other things.

(Tr. at 499-500) (emphasis added). Not only is this testimony not supported, but it is also facially misleading and prejudicial. As discussed above, the patents-in-suit are not limited to arthroscopic

devices and methods, and in fact are directed to open surgeries. ArthroCare's continual emphasis on arthroscopic products wrongly suggested to the jury that, since ArthroCare's commercial products are arthroscopic devices, Smith & Nephew's arthroscopic devices must infringe. This was unfair and misleading.

As described above, Dr. Goldberg's opinions that the use of Smith & Nephew's probes infringe the patents-in-suit lack sufficient factual support, ignore the Court's claim construction, and was not disclosed in Dr. Goldberg's expert report. Even if one accepts Dr. Goldberg's findings of infringement, it is readily apparent and uncontested that there are substantial non-infringing uses for the accused products that do not infringe the asserted claims of the patents-insuit. In fact, there are numerous non-infringing uses for each of the accused products.

Examples of uses of the accused products that do not infringe the '592, '882, and '536 patent claims are using the probes to apply energy while the return electrode is in contact with tissue, using the probes to apply energy without creating a vapor layer, and using the probes as part of an electrosurgical system that does not have a fluid supply as part of a "unitary whole" electrosurgical system.

Dr. Goldberg has testified that the accused products infringe the claims of the '592 patent because in use they are not always in contact with tissue while energy is being applied. (Tr. at 421-22). In reaching this conclusion, Dr. Goldberg recognized that the return electrode of the accused devices does frequently touch tissue while power is being applied. (Tr. at 421-22) ("as the videotape and Mr. Marsden suggested, very clearly there is occasional contact frequently ..."). It is thus uncontested that using Smith & Nephew's probes to apply energy while the return electrode is in contact with tissue is a non-infringing use of these probes even under Dr. Goldberg's description of what constitutes infringement.

Absent some evidence that these the non-infringing uses of Smith & Nephew's probes

(i.e., use with the return electrode in contact with tissue) are not substantial non-infringing uses,
no reasonable jury could conclude that Smith & Nephew is liable for contributory infringement.

H. Smith & Nephew is Not Liable for Inducement of Infringement of Any Claim of the Patents-in-Suit.

Nor has ArthroCare offered evidence sufficient to support a finding that Smith & Nephew has actively induced others to infringe any of the claims under 35 U.S.C. §271(b). To be liable for active inducement, the inducer must have "possessed the specific intent to encourage another's infringement and not merely that the defendant had knowledge of the acts alleged to constitute infringement." Manville Sales Corp. v. Paramount Sys., Inc., 917 F.2d 544, 553 (Fed. Cir. 1990). To prove inducement, ArthroCare bears the burden of proving first that Smith & Nephew's customers directly infringe, for there is no liability for inducement without a corresponding act of direct infringement. Joy Technologies, Inc. v. Flakt, Inc., 6 F.3d 770, 774 (Fed. Cir. 1993); Proctor & Gamble Co. v. Nabisco Brands, Inc., 604 F. Supp. 1485, 1487 (D. Del. 1985), overruled on other grounds, National Presto Industries, Inc. v. West Bend Co., 76 F.3d 1185 (Fed. Cir. 1996) ("There can be no liability for inducement of infringement under section 271(b) unless an actual infringement in violation of section 271(a) is induced."). ArthroCare must also prove that Smith & Nephew induced that direct infringement. Manville Sales, 917 F.2d at 553. Additionally, ArthroCare must show that Smith & Nephew had actual intent to cause the acts which constitute the infringement Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1468-69 (Fed. Cir. 1990).

ArthroCare offered no evidence that any customer of Smith & Nephew has ever used any one of the accused probes in a way that meets all of the limitations of any of the claims in suit. Indeed, the only evidence ArthroCare introduced about how Smith & Nephew customers use the products came from Smith & Nephew clinical evaluation surveys, which do not address most, much less all of the elements required by the claims. (D.I. 410 at 466, 471, and 484).

In addition, ArthroCare did not prove that Smith & Nephew intends to cause others to infringe any of the claims of the patents in suit. ArthroCare argued for the admissibility of otherwise inadmissible and highly prejudicial copying evidence, claiming that such evidence was relevant to show the intent to cause infringement element of its inducement charge. (Tr. at 24-

25). ArthroCare's "copying" story, which consisted only of an ad hominem attack and evidence that Smith & Nephew looked at certain ArthroCare products (with no evidence of actual copying), was wholly insufficient to show that Smith & Nephew actively induces any such infringement. Moreover, ArthroCare introduced no "evidence" of "copying" related to the Saphyre product.

ArthroCare also attempted to rely on evidence that Smith & Nephew instructs users to avoid contacting non-target tissue with the return electrode of the Saphyre product. (Tr. at 486). In arthroscopy, there is a well-recognized distinction between target and non-target tissue. Philip Eggers, one of the co-inventors of all three patents in suit, testified that tissue such as the meniscus is an example of target tissue and tissue such as cartilage is an example of non-target tissue. (Tr. at 351-352). Smith & Nephew does not instruct users to avoid contact with any tissue, it only instructs users to avoid contact with non-targeted tissue. Thus, ArthroCare's supposed evidence that Smith & Nephew is inducing infringement of the '592 patent claims by instructing surgeons not to contact non-targeted tissue with the Saphyre probe does not support Dr. Goldberg's conclusion, and, in fact, contradicts it.

ArthroCare's evidence is insufficient to support a finding that Smith & Nephew's customers or users actually use the accused probes in a way that directly infringes any of the claims, much less that Smith & Nephew actively induces them to do so.

I. Because The Relevant Factual Evidence Is Undisputed, This Court Should Find The Asserted Claims Of The Patents-In-Suit Invalid As A Matter Of Law

It is well recognized that a finding of invalidity requires proof by clear and convincing evidence. Mahurkar v. C.R. Bard, Inc., 79 F.3d 1572, 1576 (Fed. Cir. 1996). Nonetheless, where the relevant facts are undisputed—whether the references are prior art and what those references disclose—a jury may not simply ignore those facts to find the patent valid. See Verdegoal Brothers, Inc., v. Union Oil Company Of California, 814 F.2d 628, 632 (Fed. Cir. 1987) (granting JNOV based on the "uncontradicted disclosure" of a prior art reference); see also IPPV Enterprises, LLC v. Echostar Communs. Corp., 191 F. Supp. 2d 530, 561-62 (D. Del. 2002)

(granting JMOL based on "undisputed evidence" that the patent was invalid as anticipated and finding that no reasonable jury viewing the documentary evidence ... could fairly conclude otherwise"). If the prior art references show that all of the limitations of a patent claim are present, the trial court is required to enter JMOL of anticipation. See id.; Anderson v. Liberty Lobby, 477 U.S. 242, 250-51 (1986) ("The trial judge must direct a verdict if, under the governing law, there can be but one reasonable conclusion as to the verdict."); Richardson-Vicks, Inc. v. Upjohn Co., Civ. Action No. 93-556-SLR, 1996 WL 31209 (D. Del.), aff'd 122 F.3d 1476 (Fed. Cir. 1997). (entering JMOL of invalidity where "the evidence, viewed in a light most favorable to plaintiff, nevertheless compels a verdict contrary to that of the jury").

1. There Are No Factual Disputes Relating To Validity

In the present case, there are no factual disputes relating to validity. First, there is no dispute that the six references relied on by Smith & Nephew are prior art. Moreover, there is no real dispute about the relevant disclosures of these references, or of the patents-in-suit.

claims of the patents-in-suit is invalid. Its expert, Dr. Taylor, showed how—on a limitation-by-limitation basis—various prior art patents and articles anticipate the asserted claims of the '536 (D.I. 416 at 1294-1313), '882 (D.I. 416 at 1313-25) and '592 (D.I. 416 at 1325-34) patents.

Similarly, Dr. Manwaring, one of Smith & Nephew's other experts, also showed that the '882 patent is invalid. (D.I. 414 at 883-96). ArthroCare, on the other hand, failed to put forth any evidence to rebut Smith & Nephew's prima facie showing of invalidity, and called no witnesses to testify on validity. Thus, ArthroCare failed to meet its burden to introduce rebuttal evidence showing that the claims are valid. U.S. Environmental Prods. Inc. v. Westall, 911 F.2d 713, 716 (Fed. Cir. 1990) (holding that once a defendant demonstrates a prima facie case of invalidity, the patent holder must come forward with convincing evidence to rebut the showing); see also Hycor Carp. v. Schlueter Co., 740 F.2d 1529, 1537 (Fed. Cir. 1984).

Instead, all ArthroCare did was cross-examine Smith & Nephew's experts. But ArthroCare's cross-examination fell far short of creating a record that can support the jury's

verdict that the asserted claims are valid. Nothing brought out in the cross-examinations of Drs. Taylor and Manwaring undermined the limitation-by-limitation analysis presented by these experts. ArthroCare's counsel merely cited irrelevant concessions related to claim construction arguments that ArthroCare had proposed, and that this Court had already rejected. In light of the verdict of validity, ArthroCare's focus on irrelevant cross-examination topics clearly confused the jury, since none of these "concessions" rebutted Smith & Nephew's clear and convincing evidence of invalidity. Thus, no reasonable jury could have failed to have found the patents invalid, and the jury's verdict cannot stand. *Pannu v. Iolab Corp.*, 155 F.3d 1344, 1348 (Fed. Cir. 1998).

2. The '536 Patent

Smith & Nephew proved by clear and convincing evidence that the asserted claims of the '536 patent are invalid. Specifically, Dr. Taylor provided a limitation-by-limitation analysis of how the Elsässer and Roos Article (DTX 59A and 59B; D.I. 416 at 1294-1300), the Roos '198 patent (DTX 11; D.I. 416 at 1300-05), the Doss '007 patent (DTX 17; D.I. 416 at 1305-09), and the Pao '499 patent (DTX 21; D.I. 416 at 1309-13) each anticipate the asserted claims of the '536 patent. ArthroCare provided no rebuttal evidence to contradict Dr. Taylor's testimony, and instead relied on its cross-examination of Dr. Taylor to do nothing more than confuse the jury. However, Dr. Taylor did not waver or contradict his testimony during cross-examination, and his testimony did not provide ArthroCare with the rebuttal evidence it needed to overcome Smith & Nephew's prima facie case of invalidity.

a. The Pao '499 Patent

Perhaps the most obvious example of how ArthroCare confused and misled the jury, and of the jury ignoring the evidence with respect to the issue of invalidity involves the Pao '499 patent (DTX 21, Exhibit hereto). In his direct testimony, Dr. Taylor showed how the Pao '499 patent disclosed every limitation—on a limitation-by-limitation basis—in claims 46 and 56 of the '536 patent, as well as the unasserted independent claim 45 (D.I. 416 at 1309-13; Exhibit B).

In its cross-examination of Dr. Taylor relating to the Pao '499 patent (D.I. 416 at 1405-12), ArthroCare only asked him about one claim limitation—"the return electrode being sufficiently spaced from the electrode terminal to minimize direct contact between the return electrode and the patient's tissue." But this is a limitation that is found only in claim 47 of the '536 patent (see JTX-1, claim 47 at col. 18, lines 32-36), which is the one claim against which Smith & Nephew did not assert the Pao '499 patent. (D.I. 416 at 1728). Thus, ArthroCare's cross-examination of Dr. Taylor on this issue was completely irrelevant and misleading.

Since ArthroCare did not offer any rebuttal evidence and did not even cross-examine Dr. Taylor with respect to any other claim term, it was undisputed at trial that the Pao '499 patent anticipates claims 45, 46, and 56 of the '536 patent. Yet the jury found otherwise. Thus, JMOL of invalidity of these claims must be entered. Verdegaal Bros., 814 F.2d at 632; U.S. Environmental Prods., 911 F.2d at 716; Hycor, 740 F.2d at 1537.

b. The Doss '007 Patent

In his direct testimony, Dr. Taylor also showed how the Doss '007 patent (DTX 17, Exhibit 3) disclosed every limitation—on a limitation-by-limitation basis—of claims 45, 46, and 47 of the '536 patent. (D.I. 416 at 1305-09; Exhibit C). In its cross-examination of Dr. Taylor, ArthroCare asked him about only two claim limitations: "return electrode" and "connector located at the proximal end of the shaft." See JTX-1, claim 45 at col. 18, lines 18-22. But once again ArthroCare failed to elicit any testimony that Smith & Nephew's invalidity case.

L Return Electrode

Dr. Taylor explained that the Doss '007 patent discloses a return electrode under the Court's claim construction. (D.I. 416 1306-07, 1455-57). ArthroCare did not introduce any contrary testimony, and Dr. Taylor did not waver in his opinion on cross-examination. Instead of seeking any relevant testimony, ArthroCare asked a series of irrelevant and misleading questions regarding possible tissue effects by the return electrode. (D.I. 416 at 1380-99).

These limitations are found in independent claim 45. "Since the patentee [] does not argue the validity of the dependent claims separately, their validity will stand or fall with the independent claim [45]." Richardson-Vicks v. Upjohn Co., 122 F.3d 1476, 1480 (Fed. Cir. 1997).

First, ArthroCare asked Dr. Taylor whether the term "return electrode" was explicitly used in the Doss '007 patent. (D.I. 416 at 1380). ArthroCare was apparently trying to mislead the jury by suggesting that the words "return electrode" must be explicitly disclosed or the reference does not anticipate. This is clearly wrong, as claim limitations can be inherently found in a reference. See MEHL/Biophile Int'l Corp. v. Milgraum, 192 F.3d 1362, 1365 (Fed. Cir. 1999); see also Tyler Refrigeration v. Kysa Ind. Corp., 777 F.2d 687, 689 (Fed. Cir. 1985). Thus, ArthroCare's attempt to show that an inherent limitation is not explicitly disclosed does not rebut Smith & Nephew's anticipation case. MEHL/Biophile Int'l Corp., 192 F.3d at 1366; Verdegaal Bros., Inc. v. Union Oil Co. of Cal., 814 F.2d 628, 630 (Fed. Cir. 1987).

ArthroCare then set out on a path of questioning that not only ignored the Court's construction of the claim term "return electrode," but also reargued the claim construction that it had originally proposed and that the Court had rejected. ArthroCare had sought a claim construction that the return electrode would have minimal tissue effect. (Joint Claim Construction Statement) (D.I. 270 at 9). The Court squarely rejected ArthroCare's proposed claim construction, and instead held that "[a]s contrasted with an active electrode, the term 'return electrode' means 'an electrode having a larger area of contact than an active electrode, thus affording a lower current density." (4/19/03 Memorandum Order at 4) (D.I. 353). Yet ArthroCare ignored the Court's claim construction, and attempted to mislead the jury by asking questions related to tissue effect by the return electrode. At this point in the trial, the Court expressed some concern that the question may be misleading "because it is maybe inconsistent with what I've said." (D.I. 416 at 1389). The Court went on:

THE COURT: Well, if you are saying there is no difference between the two, I mean I do believe that under this definition there has to be a difference between the active and the return. If you are saying and your point is that in the [Doss] prior-art reference there is no difference between the two, then that is an appropriate line of cross.

ArthroCare's counsel then assured the Court that that was his intention to show specifically that there was no difference between the two electrodes. (D.I. 416 at 1389-90). However, following this interchange, ArthroCare did not attempt to show that there is no

difference between the two, but instead went right back to asking about tissue effects (D.I. 416 at 1396):

Q. So again, my question, sir, simply is, is each electrode designed to cause a tissue effect?

A. Yes.

This line of questioning is clearly misleading as it fails to take into account the Court's claim construction, which permits the return electrode to have a tissue effect. Moreover, Dr. Taylor's answer in no way contradicts his prior testimony, nor his testimony on redirect (D.I. 416 at 1455-57) (emphasis added):

Q. Did you use the Court's definition of return electrode in determining whether or not the Doss reference had a return electrode?

A. Yes.

- Q. And what is the critical element of the Court's definition of whether or not something constitutes a return electrode?
- A. The critical element is an electrode having a larger area of contact than an active electrode, thus affording a lower current density.
- Q. And when you reviewed the Doss patent, did you find such an electrode?
 - A. Yes. The outer electrode is just look at the geometry -

And just on the basis of plane geometry if you assume both electrodes have the same thickness, the outer electrode will have more surface area.

Q. And does that outer electrode meet the Court's definition of a return electrode?

A. I believe it does.

Thus, ArthroCare failed to rebut Dr. Taylor's clear and convincing testimony that the Doss '007 patent discloses a return electrode.

ii. Connector Near the Proximal End of the Shaft

Dr. Taylor testified that that the Doss '007 patent discloses a connector near the proximal end of the shaft (D.I. 416 at 1307), pointing specifically to col. 3, lines 30-34, which provides as follows:

Reference is made to Fig. 9 which schematically shows a two-electrode embodiment of the invention. A source of alternating voltage 12 such as a radio-frequency generator producing a 0.1 to 20 megahertz electric current is operably connected to electrodes 14 and 16.

This disclosure clearly meets this Court's interpretation of "connector" (4/9/03 Memorandum Order at 2) (D.L. 353):

The word connect means "to bind or fasten together; join or unite; link(.]" The word "connector," in terms of the '536 patent, shall be construed to mean a "structure that electrically links the electrode terminal to the high frequency power supply."

In its definition, the Court did not require that the connector be removable. Thus, a wire that passes through the proximal end of the device as shown in Figs. 7 and 9 of the Doss '007 patent would be a "connector" under the Court's construction.

However, in its cross-examination, ArthroCare once again ignored the Court's claim construction, and asked only whether the location of the connector was explicitly disclosed (D.I. 416 at 1400):

Q. And here in the Doss '007 patent, would you agree with me that there is no disclosure of where the connector is located, in other words, there is nothing that tells you where the connector is located with respect to the shaft?

A. Hold on a second. I believe that's correct. There is no specific mention of the location of that.

As discussed above, this is both misleading and legally incorrect because elements that are inherently disclosed still anticipate. Therefore, ArthroCare did not rebut Dr. Taylor's testimony that the Doss '007 patent discloses a connector near the proximal end of the shaft.

Verdegaal Bros., 818 F.2d at 631; IPPV Enterprises, LLC, 191 F. Supp. 2d at 561-62.

Because the return electrode and connector elements were the only ones that ArthroCare even attempted to demonstrate were not in the Doss '007 patent, and because ArthroCare patently

failed in that attempt, ArthroCare did not rebut Smith & Nephew's prima facie case that the claims 45, 46, and 47 of the '536 patent are invalid as anticipated by the Doss '007 patent and JMOL of invalidity should be entered based on this reference. U.S. Environmental Prods., 911 F.2d at 716; Hycor, 740 F.2d at 1537.

c. The Elsässer and Roos Article and the Roos '198 Patent

In his direct testimony, Dr. Taylor showed how both the Elsässer and Roos Article (DTX 59A and 59B) and the Roos '198 patent (DTX 11, Exhibit 5) disclosed every limitation—on a limitation-by-limitation basis—of claims 45, 46, 47, and 56 (Ross '198) and 45, 46, and 56 (Elsässer and Roos Article) of the '536 patent (D.I. 416 at 1294-1305; Exhibits D and E). In its cross-examination of Dr. Taylor relating to these references, ArthroCare asked him only about two claim limitations—"electrically conducting fluid" and "connector near the proximal end of the shaft." See JTX-1, claim 45 at col. 18, lines 18-25. Again, the validity of the dependent claims, which ArthroCare did not separately challenge, stands or falls with the independent claim. Richardson-Vicks, 122 F.3d at 1480. And again, ArthroCare failed to rebut Smith & Nephew's clear and convincing invalidity proof.

i. Connector Near the Proximal End of the Shaft

ArthroCare cross-examined Dr. Taylor with respect to the "connector" limitation in the Roos '198 patent, but not with respect to the Elsässer and Roos Article. In any event, it was undisputed at trial that the Roos '198 patent and the Elsässer and Roos Article both disclose a connector at the proximal end of the shaft (DTX 11 at col. 7, lines 1-7) (emphasis added):

In the present embodiment, two leads 16 pass outwards from the cylindrical neutral electrode 11, which at 20 are combined to form a single cable, leading to the rear end of the endoscope 13. The neutral electrode 11 is connected via a further insulated cable 14 to the high frequency generator...

Figure 7 and claim 1 further disclose a connector (DTX 11 at col. 7, lines 51):

insulated cable means for connecting said treatment electrode to one pole of a high-frequency generator...

Similarly, Figure 9 of the Elsässer and Roos Article clearly shows a removable connector near the proximal end of the endoscope. (DTX 59A at 133, Fig. 9) (Marsden Dec. Ex. 6)

It is clear that these disclosures in the Roos '198 patent and the Elsässer and Roos Article satisfy the limitation "connector near the proximal end of the shaft electrically coupling the electrode terminal to the electrosurgical power supply," as construed by the Court. First the Court held that the term "connector" simply means "a structure that electrically links the electrode terminal to the high frequency power supply." (4/9/03 Memorandum Order at 2) (D.I. 353). In its definition, the Court did not require that the connector be removable. Thus, a wire that passes through the proximal end of the device would be a connector under the Court's construction. The Roos '198 patent at Figure 7 and col. 7, lines 1-7 and the Elsässer and Roos Article at Figure 8 both show that all the wires lead to the rear (proximal end) of the endoscope. Thus, both references disclose a connector that is located at the proximal end of the shaft.

Second, Dr. Taylor testified that the Roos '198 patent and the Elsässer and Roos Article each disclose a connector near the proximal end of the shaft. (D.I. 416 at 1298 and 1302-03, respectively; see also Exhibits D and E). For example, Dr. Taylor explained how the Roos '198 patent discloses a connector at the proximal end of the shaft (D.I. 416 1301-03) (emphasis added):

Q. Have you done an element-by-element comparison of the teachings of the Roos '198 with the claims of the '536 patent?

A. Yes, I have.

A. ... A connector, requires a connector, coupling the shaft to the electrosurgical power supply. And that element is satisfied by Figure 7 and the text in Column 7, Lines 1 through 5. And also in Claim 1, as described here in this text. So that element is satisfied.

Dr. Taylor also explained that the disclosure of the connector in the Roos '198 patent was inherent (D.I. 416 at 1371-72):

- A. You do realize that all resectoscopes have connectors at the back end of the resectoscope.
- A. There is nothing in the '198 patent that says it explicitly. But there are no resectoscopes on the market that don't have a connector at the end, on the back of the resectoscope.

ArthroCare again did not introduce any contrary testimony and Dr. Taylor never wavered in his opinion. Instead, ArthroCare only asked whether the location of the connector was explicitly described in the Roos '198 patent (D.I. 416 1371). These questions were irrelevant since elements do not have to be explicitly recited to be found in a prior art reference. See MEHL/Biophile, 192 F.3d at 1365; Tyler Refrigeration, 777 F.2d at 687.

Further, ArthroCare did not present any evidence, not even through cross-examination, to contradict Dr. Taylor's testimony that the Elsässer and Roos Article discloses a connector at the proximal end of the shaft. And ArthroCare did not ask a single question about the connector's location in the Elsässer and Roos Article.

ii. Electrically Conducting Fluid

The other issue on which ArthroCare cross-examined Dr. Taylor related to the "electrically conducting fluid" limitation. Despite ArthroCare's lengthy cross-examination of Dr. Taylor, it was undisputed at trial that claim 1 of the Roos '198 patent and the Elsässer and Roos Article both explicitly disclose electrically conducting fluid. Claim 1 of the Roos '198 patent reads:

[A] space being formed between said treatment electrode and said neutral electrode which is adapted to be filled with *liquid to provide electrical* conductance between said electrodes.

(DTX 11 at col. 7, lines 59-62) (emphasis added). Similarly, the Elsässer and Roos Article also explicitly discloses electrically conducting fluid:

[The device] offer[s] the high-frequency current a path to balance the potential difference that would be so short and offer such a low resistance that aberrant currents or leakage currents do not even occur... The current flows directly from the cutting loop to the neutral electrode through the adjacent tissue to be cut and the irrigation liquid.

(DTX 59B at 4) (emphasis added).

It is clear that the "liquid to provide electrical conductance" in claim 1 of the Roos '198 patent and the "irrigation liquid" which "offer[s] such a low resistance" in the Elsässer and Roos Article are both the same as "electrically conductive fluid" as used in the '536 patent, for at least two reasons.

First, the words used in claim 1 of the Roos '198 patent and in the Elsässer and Roos Article both clearly meet this Court's interpretation of "electrically conductive fluid" (4/9/03 Memorandum Order at 3) (D.I. 353):

"[E]lectrically conducting fluid" and "electrically conductive fluid" shall be construed to mean "any fluid that facilitates the passage of electrical current."

In its definition, all the Court required was that the fluid "facilitate[] the passage of electrical current." Of course, a "liquid" is a type of "fluid," and since "facilitate" means simply "to make easier," a "liquid to provide electrical conductance" in claim I of the Roos '198 patent squarely meets this Court's definition of "any fluid that facilitates the passage of electrical current." Similarly, the "irrigation liquid" that "offer[s] such a low resistance" would clearly "facilitate the passage of electrical current."

Second, the testimony at trial was undisputed that the Roos '198 patent and the Elsässer and Roos Article both disclose the use of electrically conducting fluid. Dr. Taylor testified that the Roos '198 patent and the Elsässer and Roos Article each disclose electrically conducting fluid. (D.I. 416 at 1299 and 1303, respectively). For example, Dr. Taylor explained that claim 1 of the Roos '198 patent explicitly discloses electrically conducting fluid (D.I. 416 at 1301-03) (emphasis added):

A. ... The Roos '198 patent basically follows up on the work that Doctors Elsasser and Roos did in their article and it's a bipolar electrosurgical device for the treatment of prostate and bladder tissue, commonly known as TURP.

It also requires an electrically conducting fluid supply, directed to the target site and generating current, flow path between the active and return electrode. That is diagrammatically shown here in Figures 7 and 8 and also specifically called out in Claim I, basically the last line in Claim I. So that element is satisfied.

Q. Just to pause on this one for a moment, that language that is quoted below the [demonstrative exhibit] drawing comes from Claim 1 of the Roos '198 patent?

- A. That's correct.
- Q. That is where you found support for the electrically conduct[ing] fluid limitation?

A. Yes.

ArthroCare did not introduce any contrary testimony, and did not call its own expert Dr.

Goldberg to testify in rebuttal to Smith & Nephew's invalidity case. Dr. Taylor never changed his opinion. Instead, ArthroCare's strategy was to once again mislead the jury by having Dr.

Taylor "admit" irrelevant facts that in no way contradicted or overcame the fact that these references disclose electrically conducting fluid.

For example, Dr. Taylor testified under cross-examination that the Roos '198 patent and the Elsässer and Roos Article do not use the words "saline" or "ringer's lactate." (D.I. 416 at 1375). However, this line of questioning was misleading since the asserted claims of the '536 patent do not require that the electrically conducting fluid be saline or ringer's lactate. Thus, ArthroCare failed to rebut Dr. Taylor's clear and convincing testimony that these references disclose an electrically conducting fluid under the Court's claim construction.

ArthroCare also questioned Dr. Taylor about how some other prior art monopolar TURP devices used glycine or other non-conductive fluids (D.I. 416 at 1339), apparently trying to suggest some connection between TURP procedures and non-conductive fluids. However, such a suggestion does not change the unchallenged fact that claim 1 of the Roos '198 patent explicitly discloses using electrically conducting fluid as Dr. Taylor testified.

ArthroCare also attempted to confuse the jury by pointing to embodiments in the Roos '198 patent that used contact between the return electrode and the tissue to provide some of the electrical connection. (D.I. 416 at 1345). However, Dr. Taylor pointed out that "this is not the embodiment that I talked about and it's not an embodiment that I described." (Id.). ArthroCare's focus on other embodiments is misleading. It is well-settled that all that is needed to anticipate is one anticipating embodiment or disclosure, even if other embodiments might not anticipate. See

¹³ The saline limitation is found only in asserted claims 11 and 32 of the '592 patent. The references Smith & Nephew relied upon for anticipation of the '592 patent, the Doss '007 patent and the Slager article, explicitly disclose saline.

¹⁴ The Roos '198 patent and Elsässer and Roos Article both describe devices that can be used in procedures other than TURP (DTX-11 at Col. 1, lines 18-22; DTX-59B at 5).

Ultradent Prods., Inc. v. Life-Like Cosmetics, Inc., 127 F.3d 1065, 1068 (Fed. Cir. 1997) (holding that the district court erred in limiting the disclosure to the non-anticipating preferred embodiment when the other embodiments may anticipate). Therefore, this line of questions also did not rebut Dr. Taylor's direct testimony.

Finally, ArthroCare pointed to a later-issued patent, the Roos '667 patent. (PX-605) (Tr. at 1359-70). However, Dr. Taylor testified that the Roos '667 patent was irrelevant to his opinion that electrically conductive fluid was used in the Roos '198 patent (D.I. 416 at 1365-66) and ArthroCare adduced no evidence to the contrary.

None of Dr. Taylor's cross-examination testimony in any way contradicted his direct testimony, or the explicit disclosures of the references, that both the Roos '198 patent and the Elsässer and Roos Article clearly disclose an electrically conducting fluid. Thus, because ArthroCare put on no other evidence on this point, ArthroCare has not rebutted Smith & Nephew's prima facie case that the asserted claims of the '536 patent are invalid as anticipated by the Elsässer and Roos Article and the Roos '198 patent, and JMOL of invalidity of claims 46, 47, and 56 based on these references is clearly warranted. U.S. Environmental Prods., 911 F.2d at 716; Hycor, 740 F.2d at 1537.

3. The '882 Patent

Smith & Nephew also proved by clear and convincing evidence that the asserted claims of the '882 patent are invalid. Specifically, Dr. Taylor provided a limitation-by-limitation analysis of how the Manwaring '138 patent (DTX 46; D.I. 416 at 1313-17) anticipates claims 1, 13, and 54 and the Slager Article (DTX 65; D.I. 416 at 1317-20) anticipates claims 1, 13, 17, and 54 of the '882 patent. Dr. Manwaring, one of Smith & Nephew's other experts, also testified that the Manwaring '138 patent anticipated claims 1, 13, and 54 of the '882 patent. (D.I. 416 at 886-96). Dr. Taylor further testified that the asserted claims are invalid as not enabled under 35 U.S.C. § 112, because the supposed new process of "coblation" is not adequately described to differentiate it from the prior art. (D.I. 416 at 1320-25).

ArthroCare once again provided no rebuttal evidence to contradict Dr. Taylor's and Dr. Manwaring's testimony, and instead relied on its cross-examination of these experts to confuse —d mislead the jury. However, neither Dr. Taylor nor Dr. Manwaring wavered or contradicted their testimony during cross-examination, and their testimony went unrebutted.

a. The Slager Article

In its cross-examination of Dr. Taylor relating to the Slager Article (DTX 65),

ArthroCare asked about two claim limitations—"at least a portion of the energy induced is in the form of photons having a wavelength in the ultraviolet spectrum" and "evacuating fluid generated at the target site": as well as a portion of the preamble to claim 1 of the '882 patent—"applying energy to a target site on a patient body structure." However, ArthroCare failed to rebut Smith & Nephew's prima facie case of invalidity of the '882 patent.

L UV Photons

Dr. Taylor testified that the Stager Article discloses energy in the form of photons having a wavelength in the ultraviolet spectrum (UV photons), which is a limitation in claim 13. (D.I. 416 at 1319; Exhibit F). ArthroCare did not introduce any contrary testimony. Instead, ArthroCare attempted to mislead the jury by suggesting that, because UV photons were not explicitly disclosed, UV photons were not present at all. (D.I. 416 at 1419-21).

However, Dr. Taylor explained, in detail, why the production of UV photons is inherently disclosed in the Slager Article based on principles of elementary chemistry:

- Q. So just from seeing a spark, just from seeing that flash of light with the naked eye, you can't tell whether or not there is ultraviolet light in there or whether there isn't. True?
- A. That's true, except you can't have a spark in aqueous solution without the UV light.
- Q. So you didn't do any tests and you didn't look at the literature; correct?
- A. Right. One has to realize, though, that if you have a spark in an aqueous solution, especially a sodium chloride aqueous solution, that you will generate UV photons because of the transition of the hydroxyl ion. You will

also generate what we would consider to be orange, yellowish-orange light, 580 nanometers, because of the sodium ion transition. That is college chemistry.

(D.I. 416 at 1419-20) (emphasis added).

Dr. Taylor's testimony that the Slager Article inherently discloses the production of UV photons was not rebutted by ArthroCare, and therefore, for purposes of anticipation analysis, it does contain that limitation. See generally Verdegaal Brothers, 814 F.2d at 631 (holding that a patent claim is anticipated by a reference that either explicitly or inherently discloses all of the claim limitations).

ii. Evacuating Fluid Generated at the Target Site

Dr. Taylor also testified that the Slager Article discloses evacuating fluid (bubbles) generated at the target site, which is a limitation in claim 54. (D.I. 416 at 1320; Exhibit F). ArthroCare did not introduce any contrary testimony and Dr. Taylor never wavered on cross-examination. Instead, ArthroCare again attempted to mislead the jury by suggesting that, because the exact suction technique was not explicitly disclosed, that a suction lumen adjacent the electrode terminal is not disclosed. (D.I. 416 at 1425-26).

iii. Applying Energy to a Patient Body Structure

Dr. Taylor testified that the Slager Article anticipates claim 1 of the '882 patent. (Tr. at 1319; Exhibit F). Again, ArthroCare did not introduce any contrary testimony and instead attempted to mislead the jury by suggesting that, because the tissue used by Slager was a piece of aorta in a lab dish, the Slager Article did not disclose a "method for applying energy to a target site on a patient body structure" as set forth in the preamble of the '882 patent. (Tr. at 1426-28).

The reference to "patient body structure" merely sets forth the intended environment of use in the preamble of the claim, and does not constitute a claim limitation. See Allen Eng'g Corp. v. Bartell Indus., Inc., 299 F.3d 1336, 1346-47 (Fed. Cir. 2002); Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368, 1373-75 (Fed. Cir. 2001).

Moreover, ArthroCare's suggestion is completely undercut by the position it took with respect to conception and reduction to practice of claim 1 of the '882 patent. In particular, in

order to avoid some of Smith & Nephew's prior art, ArthroCare asserted that claim 1 of the '882 patent was reduced to practice by June 18, 1993. (DTX 406). However, Philip Eggers, one of the inventors of the patents-in-suit, testified that as of 1993 his experiments had not progressed to being used in live patients, but only involved chicken parts in bowls of saline (D.L 410 at 295);

Q. My question to you, Mr. Eggers, is: As of January 25, 1993, or February 8, 1993, the development of your invention had not progressed to the point that it was being used on actual patients; right?

A. That's correct.

Q. It was only being used in experiments in bowls of saline on various chicken parts; right?

A. Correct.

Thus, the inventor himself believed that experiments in bowls of saline were covered by methods of applying energy to a target site on a body structure. ArthroCare cannot have it both ways. If experiments on chicken parts in bowls of saline were sufficient to constitute reduction to practice of a "method for applying energy to a target site on a patient body structure," then a prior art method involving human acrta tissue in a lab dish certainly must also qualify as such a method. Accordingly, ArthroCare did not rebut Dr. Taylor's testimony, nor did it contradict his conclusion that the Slager Article anticipates the asserted claims of the '882 patent.

Therefore, ArthroCare failed to rebut Smith & Nephew's prima facie case of invalidity based on the Slager Article, and JMOL of invalidity of claims 13, 17, and 54 based on this reference is warranted. U.S. Environmental Prods., 911 F.2d at 716; Hycor, 740 F.2d at 1537.

b. The Manwaring '138 Patent

In its cross-examination of Dr. Taylor relating to the Manwaring '138 patent (DTX 46),

ArthroCare asked him about two claim limitations—"at least a portion of the energy induced is in
the form of photons having a wavelength in the ultraviolet spectrum" and "evacuating fluid
generated at the target site." ArthroCare also asked about these same two limitations in its cross-

¹⁵ Claim 1 of the '882 patent was reduced to practice in June 1993, and there is no evidence that the invention progressed to use in live patients in that time. Further, the language in the '592

examination of Dr. Manwaring. However, ArthroCare failed to rebut Smith & Nephew's invalidity case in either cross-examination, and did not introduce any rebuttal evidence of its own.

i. UV Photons

Dr. Taylor testified that the Manwaring '138 patent discloses UV photons. (D.I. 416 at 1316; Exhibits G and H). ArthroCare did not introduce any contrary testimony. Instead, ArthroCare attempted to mislead the jury by suggesting that, because Dr. Taylor did not test for UV photons, UV photons were not present at all. (D.I. 416 at 1429). However, as discussed above, Dr. Taylor explained why UV photons are inherently present when you have sparking in an aqueous solution, such as the sparking found in the Manwaring '138 patent, as a matter of elementary chemistry. (See D.I. 416 at 1316 and DTX 46 at col. 6, lines 50-63).

Dr. Taylor's opinion was corroborated by Dr. Manwaring. (D.I. 414 at 893-95 and 917-19). ArthroCare did not introduce any contrary testimony and Dr. Manwaring also never wavered on cross-examination. Instead, ArthroCare attempted to mislead the jury by suggesting that, because UV photons were not explicitly disclosed, UV photons were not present at all. (D.I. 414 at 897-98). But making such a suggestion does not satisfy ArthroCare's obligation to introduce evidence relating to validity. Verdegaal Bros., 814 F.2d at 631; IPPV Enterprises. LLC, 191 F. Supp. 2d at 561-62.

Thus, ArthroCare failed to rebut the testimony of either Dr. Taylor or Dr. Manwaring regarding the inherent presence of UV photons.

ii. Evacuating Fluid Generated at the Target Site

Dr. Taylor testified that the Manwaring '138 patent discloses evacuating fluid generated at the target site. (D.I. 416 at 1316-17; Exhibits G and H). ArthroCare did not introduce any contrary testimony. Instead, ArthroCare attempted to obfuscate the issues and mislead the jury by suggesting an improper limitations to this claim.

patent, which was reduced to practice in February 1993, includes almost identical language: "method for applying energy to a target site on a body structure on or within a patient's body."

First, AnthroCare attempted to mislead the jury by suggesting that all of the fluid at the target site must be evacuated (D.I. 416 at 1432-33) (emphasis added):

Q. Right. But you are not going to take the fluid from this region at the tip and suck all of the fluid way over here, way up into the device and leave no fluid down at the tip, are you? You're going to suck fluid in, so that electrode tip has some fluid in contact with it; right?

A. Oh, yes.

ArthroCare asked similarly misleading questions of Dr. Manwaring during his cross-examination (D.L. 414 at 904-05):

Q. So isn't it fair to say, then, that [sic] fluid remains at or on the target site, that you are trying to treat in the course of a surgery?

A. That's correct.

This was clearly misleading because there is no requirement that all of the fluid be evacuated.

(See JTX-2 at claim 54 and col. 23, lines 24-33). ArthroCare's misleading suggestion does not overcome Dr. Taylor's and Dr. Manwaring's testimony that the Manwaring '138 patent discloses evacuation.

Second, ArthroCare tried to suggest that what is evacuated is not fluid generated at the target site, but rather the electrically conducing fluid (D.L. 414 at 903-04). This suggestion is irrelevant and misleading because, as Dr. Manwaring explained, the lumen would evacuate a mixture including saline as well as fluid that was generated at the target site (D.L. 414 at 921-21):

- Q. Would there be some fluid that was removed from the target site?
- A. Yes. Fluid would always be there, and the evacuation, whether it is sucking, essentially pulls fluid which is salt laden, electrically conductive, by the electrode. That's the principle.
 - Q. Do you consider that evacuation?
 - A. Yes.
- Q. Now, the fluid that is evacuated, would that include fluid that was generated at the target site?
 - A. It can.
 - Q. What kind of fluid would that include?

A. Well, heating in the presence of biologic tissue. Let's say one is ablating, which means removing, tumor tissue in the brain. That tissue is vaporized. And in that vaporization is fluid in the form of gas, which quickly mingles with the spinal fluid or the irrigated normal saline. So it's a mix again.

This is consistent with the explicit disclosure of the '882 patent. (JTX-2 at col. 23, lines 30-34). Thus, ArthroCare failed to rebut the testimony of either Dr. Taylor or Dr. Manwaring regarding the evacuation of fluid generated at the target site.

Therefore, ArthroCare failed to rebut Smith & Nephew's prima facie case of invalidity of the asserted claims based on the Manwaring '138 patent and the Court should enter JMOL that claims 13 17, and 54 are anticipated. U.S. Environmental Prods., 911 F.2d at 716; Hycor, 740 F.2d at 1537.

c. Enablement

Dr. Taylor also testified that the '882 patent is invalid for lack of enablement. (D.I. 416 at 1320-25). The test for whether patent claims are enabled is whether the specification teaches those of ordinary skill in the art how to make and use the full scope of the invention without undue experimentation. *In re Wands*, 858 F.2d 731, 736-37 (Fed. Cir. 1988).

The specification explains that the process of the '882 results in phenomenon the inventors called "cold ablation," which "can be precisely controlled to only affect a thin layer of cells without heating or otherwise damaging surrounding or underlying cells." '882 patent at 11:38-41.

The specification itself essentially establishes the enablement problem:

The necessary conditions for forming a vapor layer near the active electrode tip(s), ionizing the atom or atoms within the vapor layer and inducing the discharge of energy from plasma within the vapor layer will depend on a variety of factors, such as: the number of electrode terminals; electrode size and spacing; electrode surface area; asperities and sharp edges on the electrode surfaces; electrode materials; applied voltage and power; current limiting means, such as inductors; electrical conductivity of the fluid in contact with the electrodes; density of the fluid; and other factors.

Id. at 11:4-13. The specification further explains that the ionizaton induces the discharge of energetic electrons only "under optimal conditions." Id. at 10:65-66.

Despite this requirement of "optimal" conditions, the specification fails to specify what particular parameters should be used. Instead, the specification gives large ranges of parameters for nine different variables, with no guidance as to what particular combinations would result in the "optimal conditions" required for cold ablation.

Despite using this term in the patent, the evidence showed that ArthroCare itself recognized that the method of operation of its invention is not new at all, but identical to the prior art. ArthroCare has frequently backed off of this "cold ablation" assertion. Specifically, as Dr. Taylor explained, the principle of operation of the System 970, which ArthroCare asserts is covered by the patents-in-suit Tr. 1505 is the same as how prior art devices work (D.I. 416 at 1323) (emphasis added):

- Q. Do you have any opinion as to whether ArthroCare's description of the mode of operation or the principle of operation of its System 970 is consistent with the opinion that you have offered here in court in this morning?
- A. Yes. Essentially, the opinion that I have, I think what is confirmed here in the text, is that the system operates in the same manner as a conventional electrosurgical system, use of arcing and such, that is described by what is known as prior art, stuff that has been known for a long time.

With this understanding, and admission that the allegedly patented devices operate like prior art electrosurgical devices, Dr. Taylor, who was clearly qualified as one of skill in the art [cite], testified that if ArthroCare tried to distinguish its patents over the prior art based on its alleged "Coblation" phenomenon, the claims would not be enabled (D.I. 416 at 1324-25):

- Q. Do you have an opinion as to whether the claims of the '882 patent are enabled to the extent it claims a new phenomenon?
 - A. Yes, I have an opinion.
 - Q. What is that opinion?
 - A. That it is not.

On cross-examination, Dr. Taylor did not contradict this testimony. ArthroCare's counsel merely cross-examined him on a laundry list of preferred embodiment parameters that were included in the '882 patent. (D.L 416 at 1436-38). However, this did not rebut Dr. Taylor's testimony in any way. None of these preferred embodiment parameters discloses how one skilled

in the art duplicating the device would get a device that produces "Coblation" instead of the prior art arcing described in ArthroCare's principle of operation.

Further, if one were to build a device within the preferred embodiment parameters of the '882 patent, the result would simply be the device of the prior art Manwaring '138 patent. Here is a comparison of the most preferred embodiment of the '882 patent to the disclosure in the Manwaring '138 patent:

Preferred element	'882 Patent	The Manwaring '138 Patent
Active electrode surface area	1 to 20 mm ² (15:37-39)	1.4 mm ² (5:20-27)
Active electrode spaced from tissue	0.05 to 0.5 mm (15:63-66)	0 to 2 mm (5:55-61 and 6:53-57)
Active electrode may be flush with probe surface	(16:55-56)	(5:55-61)
Active electrode may be recessed from surface	0.01 to 0.2 mm (16:57-60)	0 to 2 mm (5:55-61)
Active electrode may be several materials	platinum, titanium tantalum or tungsten (16:64-66)	stainless steel or tungsten (5:20-21)
Fluid is preferably saline	(12:38-40)	(7:6-8)

Thus, ArthroCare did not rebut Smith & Nephew's prima facie case of invalidity based on non-enablement, and the Court should enter JMOL. See generally, Enzo Biochem., Inc. v. Calgene, Inc., 188 F.3d 1362, 1374 (Fed. Cir. 1999) (finding that "[t]ossing out the mere germ of an idea dos not constitute enabling disclosure" and that "reasonable detail must be provided in order to enable members of the public to understand and carry out the invention").

4. The '592 Patent

Smith & Nephew also proved by clear and convincing evidence that the asserted claims of the '592 patent are invalid. Specifically, Dr. Taylor provided a limitation-by-limitation analysis of how the Doss '007 patent (DTX 17; D.L 416 at 1325-30; Exhibit I) and Stager Article (DTX 65; D.L 416 at 1330-34; Exhibit I) each anticipate the asserted claims of the '592 patent.

ArthroCare again provided no rebuttal evidence to contradict Dr. Taylor's testimony, and instead

relied on its cross-examination of Dr. Taylor to confuse and mislead the jury. However, Dr. Taylor did not withdraw or contradict his testimony during cross-examination.

a. Doss '907

In its cross-examination of Dr. Taylor relating to the Doss '007 patent (DTX 17),

ArthroCare asked about only two claim limitations—"return electrode" and "voltage [] in the range from 500 to 1400 volts peak to peak." See, e.g., JTX-3, claims 1 and 21. But once again ArthroCare failed to elicit any testimony to rebut Smith & Nephew's invalidity case.

i. Return Electrode

The '592 patent contains the same "return electrode" limitation as the '536 patent, discussed above at Section 2(b)(i). And as with the '536 patent, ArthroCare did not rebut Dr. Taylor's testimony that the Doss '007 patent discloses a return electrode. Further, this limitation is found in independent claim 1. Since ArthroCare did not argue the validity of claims 3, 4, or 11 separately, their validity will stand or fall with independent claim 1. Richardson-Vicks, 122 F.3d at 1480.

ii. Voltage in the Range From 500 to 1400 Volts

Dr. Taylor testified that the Doss '007 patent inherently discloses a voltage in the range from 500 volts to 1400 volts peak to peak. (D.L 416 at 1330). ArthroCare put on no evidence to rebut this testimony. Instead, ArthroCare once again limited its cross-examination to simply showing that the limitation was not expressly disclosed, ignoring the settled law that a limitation can be present in anticipating prior art inherently. MEHL/Biophile, 192 F.2d at 1365.

As explained by Dr. Taylor, instead of disclosing the peak to peak voltage, the Doss '007 patent discloses a voltage of 20 to 200 volts RMS (root-mean-square). To convert from voltage expressed in RMS, one needs to multiply by 2.83 to get voltage expressed in peak-to-peak units. (D.I. 416 at 1330). This conversion results in a voltage of 560 volts peak-to-peak for the Doss '007 patent. (Id.). ArthroCare attempted to confuse the jury regarding this inherent disclosure by

asking Dr. Taylor whether the Doss '007 patent expressly disclosed a sine wave, which is the most common waveform used. (D.I. 416 at 1402). Dr. Taylor maintained his opinion (id.):

- Q. And there is nothing in the Doss patent that says that a sine wave is used with this generator; correct?
 - A. That's correct.
- Q. So we don't know whether there is a sine wave here or a square wave or some other waveform; right?
- A. You're correct. But, to my knowledge, there are no commercially-available square wave generators.

Thus, ArthroCare failed to rebut Dr. Taylor's testimony that the Doss '007 patent inherently discloses a voltage of from 500 to 1400 volts peak-to-peak.

Therefore, ArthroCare has not rebutted Smith & Nephew's prima facie case that the asserted claims of the '536 patent are invalid as anticipated by the Doss '007 patent, and JMOL based on this reference is clearly warranted. U.S. Environmental Prods., 911 F.2d at 716; Hyeor, 740 F.2d at 1537.

b. Slager Article

In its cross-examination of Dr. Taylor relating to the Slager Article (DTX 65),

ArthroCare asked only about one claim limitation—"spacing a return electrode away from the
body structure in the presence of the electrically conductive fluid"; and the preamble language—
"applying electrical energy to a target site on a body structure on or within a patient's body." See

JTX-3 at claim 23. ArthroCare again failed to elicit testimony sufficient to rebut Smith &

Nephew's invalidity case. Further, this limitation is found in independent claim 23. Since

ArthroCare did not argue the validity of claims 26, 27, 32, or 42 separately, their validity will

stand or fall with independent claim 1. Richardson-Vicks, 122 F.3d at 1480

Applying Energy to a Target Site on a Body Structure on or Within a Patient's Body

The '592 patent contains the same "on or within a patient's body" limitation as the '882 patent. And as discussed above with respect to the '882 patent in Section F(3)(a)(iii), ArthroCare

did not rebut Dr. Taylor's testimony that the Slager Article discloses a method for applying energy to a target site on a body structure on or within a patient's body.

ii. Spacing a Return Electrode Away from the Body Structure in the Presence of the Electrically Conductive Fluid

The Slager Article expressly discloses that a section of aortic tissue approximately 4 by 7 centimeters in size was used in an in vitro experiment. (DTX 65 at 1382.) The article also discloses that the spacing between the active electrode and return electrode varied between 2 to 10 centimeters. (Id. at 1383.) Thus, when the distance between the electrodes was 7 centimeters or more, the return electrode was necessarily not touching the aortic tissue sample. Dr. Taylor testified that the Slager Article discloses spacing a return electrode away from the body structure in the presence of the electrically conductive fluid. (D.I. 416 at 1331). ArthroCare did not introduce any testimony to the contrary. Instead, ArthroCare asked Dr. Taylor a series of misleading cross-examination questions regarding an experiment described in the Slager Article on which Dr. Taylor was not basing his testimony.

Specifically, the Slager Article describes both an in vitro and an in vivo experiment. (See DTX 65). These are two different experiments. Dr. Taylor based his opinion of invalidity on the in vitro experiment. His testimony on this point could not have been clearer. (D.I. 416 at 1414):

- Q. And the portions of this article that you were saying were relevant to the '882 and the '592 patent related to the *in vitro* test; correct? Not to the test on the pig?
 - A. You said the in vitro test?
 - Q. I did.
 - A. Yes.
 - Q. Okay. The in vitro means what in this article?
- A. In vitro means it's outside the body, generally in a dish preparation of some sort. I guess it's the opposite of in vivo, which is inside the body.

ArthroCare's counsel nevertheless went on to ask misleading questions about the irrelevant in vivo experiment, which did not form any part of the basis for Dr. Taylor's testimony (D.L 416 at 1416-18). The jury may have been misled to believe that because the *in vivo*

experiment did not disclose all of the limitations, the same is true for the *in vitro* test. While the jury may have been misled, this cross examination did not rebut Dr. Taylor's clear testimony that the *in vitro* test in the Slager Article discloses a return electrode spaced away from the body structure in the presence of the electrically conductive fluid, nor does it rebut the explicit disclosure of the Slager Article. See Ultradent Prods., 127 F.3d at 1068 (a reference anticipates if any one embodiment anticipates, even if other embodiments do not).

Thus, ArthroCare did not rebut Smith & Nephew's prima facie case that the asserted claims of the '592 patent are invalid as anticipated by the Slager Article, and JMOL is warranted based on this reference. U.S. Environmental Prods., 911 F.2d at 716; Hycor, 740 F.2d at 1537.

V. CONCLUSION

For the foregoing reasons, Smith & Nephew respectfully requests that the Court enter Judgment as a Matter of Law that the '882 certificate of correction is invalid, that the accused products do not infringe the asserted claims, that the asserted claims of the '536 and '592 patent are anticipated by the prior art, and that the asserted claims of the '882 patent are not enabled and are anticipated by the prior art.

Dated: June 30, 2003

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CERTIFICATE OF SERVICE

I hereby certify that on this 30TH day of June, 2003, a true and correct copy of SMITH &

NEPHEW'S OPENING BRIEF IN SUPPORT OF ITS RULE 50(b) MOTION FOR

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1

Anticipation by The Pao '499 Patent DTX-21

1	Total Constitution	Smith & Nonkew's Evidence	ArthroCare's Position
	The Court's Cistain Constitution	The Pan 499 abstract generally describes	ArthroCare did not offer any
ioi E	Life court signi apply use of chimal	the Pan invention as an electrosurgical	rebuttal evidence or dispute
applying electrical energy to a	delimition of the term system. The	derice used in electrocautery and	that Pao '499 met the
target site on a structure	term aystem shall be consumed to	electrocosmistion operations. See also.	preamble at trial.
within or on a patient's body,	mean an exemplage of	Col 1 lines 15-18 and Claim 1. All of	•
the system comprising:	combination of trungs or parts	the state of the s	
	forming a unitary whole," D.L. 353	the components, including the little	
	at 5.	supply, are combined as a unitary whole	•
		in the probe.	
		Dr. Taylor's testimony at Tr. 1310	
	The Court did not construe this	Pao '499 discloses a high frequency	ArthroCare did not offer any
a right frequency power	I to the state of	hingler nower sumply throughout. See.	rebuttal evidence or dispute
supply:		+ 6 Apl 7 limes 15-36	that Pao '499 met this
			limitation at trial.
		Dr. Laylor's testimony at 11, 1310-11.	8
an electromismical marks	"The term 'distal end' shall be	Pao '499 discloses an electrode assembly	ArthroCare did not offer any
all closusous growth professions	batarity has edit mean of bountaines	portion (shaft) having a terminal region	rebuttal evidence or dispute
COMPTTSING & SUBIL MAYING &		(dietal and) and a proximal end. See col.	that Pao '499 met this
proximal end and a distal end,	away irom the point of or \$100		limitation of triple
	attachment. The term 'proximal	7, lines 6-9; col. 7, lines 13-30; see also	imitation at u.a.:
	end' shall be construed to mean 'the	Fig. 7, which generally shows a distal	
	and aimsted towards the point of	end and proximal end.	
	City of other base 7" D 1 353 of		
	origin of autominent.	Dr. Taylor's testimony at Tr. 1311.	
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Anticipation by The Pag '499 Patent DTX-21

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Position	d not offer a	nce or dispu	met this rial.								id not offer	ing not offer ence or disp met this trial.		
ArthroCare's Position	ArthroCare did not offer any	rebuttal evidence or dispute	that Pao '499 met this limitation at trial.									Arthrocare and not outer any rebuttal evidence or dispute that Pao '499 met this limitation at trial.		
	Smith & Nepnew's Evidence	Ble		(shaft), See, e.g., col. 7, lines 15-19; see	also rig. 9, which generally shorts and a saint electrode 236 (electrode terminal) at	the terminal region 254 (distai) end of the electrode assembly 212 (shaft).	Dr. Taylor's testimony at Tr. 1311.			-		Pao '499 discloses an electrical connection portion 220 (connection) near the proximal end of the shaft, which couples the axial electrode (electrode terminal) to the high frequency power	supply. See, e.g., col. 7, innes 23-37; col. 6, lines 8-13; see also Figs. 7, which shows the pins at the proximal end.	Dr. Taylor's testimony at Tr. 1311.
İ	흹	"Consistent with the intrinsic	evidence of the patents in suit, electrode terminal, means one of	more touve electrodes. Lat. 33 at 33.	"The court shall apply the ordinary	definition of the term 'active	term active electrode means 'a	simulating cross con risely for stimulation and	distinguished from [a return	electrode] by having a smaller area	or contact, with "Td.	or fasten together; join or unite; or fasten together; join or unite; link[.]. The word 'connector,' in terms of the '536 patent, shall be construed to mean 'a structure that	electrically links the electrode terminal to the high frequency power supply." D.I. 353 at 2.	
	Patent		el end,				-					a comector near the proximal end of the shaft electrically coupling the electrode terminal to the electrosurgical	power supply:	

Anticination by The Pao '499 Patent DIX-21

		Cmith & Nanhow's Fvidence	ArthroCare's Position
Claim 45 of the '536 Patent	Ment The Court's Claim Construction Smith & McPack Street		A sthronger did not offer any
a renum electrode electrically	! "As contrasted with an active		לוייי ואויס ואוי חוח חוח חווייי
	electrode the term 'retim electrode'	aleaneds the term trentm electrode (return electrode) at the terminal region	rebuital evidence or dispute
	mesne 'en electude having a larger	(distal end), which is electrically coupled that Pao '499 met this	that Pao '499 met this
power suppry, and	area of contact than an active	to the high frequency generator by the	limitation at trial.
	electrode thus affording a lower	pins and female connector. See, e.g., col.	
	current density." D.J. 353 at 4.	7, lines 13-19; col. 7, lines 25-37; col. 6,	
		lines 8-13. The outer electrode has a	
•		larger area of contact than the axial	
		(active) electrode.	
		Dr. Taylor's testimony at Tr. 1311.	

Anticipation by The Pso '499 Patent DTX-21

The At At At the At A Dotont	The Court's Claim Construction	Smith & Nephew's Evidence	ArthroCare's Position	
	"Consistent with the prosecution history, the phrase 'electrically conducting fluid supply' shall be construed to mean 'a medical container that stores electrically conducting fluid." An example of a medical container is an IV bag. An example of electrically conducting fluid is isotonic salme." D.I. 353 at 2.	pao '499 discloses a central lumen 260 in the axial electrode (electrode terminal) that is coupled to an electrically conducting fluid supply, such as a botle direct the saline solution, which will direct the saline to the target site to generate a current flow path between the outer electrode (return electrode) and the axial electrode (electrode terminal). See col. 7, lines 21-25, col. 7, lines 63-67; col. 8, lines 36-67;	ArthroCate did not older any rebuttal evidence or dispute that Pao '499 met this limitation at trial.	
	"Consistent with the ordinary definition, 'electrically conducting fluid' and 'electrically conductive fluid' shall be construed to mean 'any fluid that facilitates the passage of electrical current.' Examples of electrically conducting fluids are blood and saline." Id. at 3.	Dr. Taylor's testimony at Tr. 1311-12.		
	Directing or delivering the electrically conductive fluid to the target site "shall be construed consistent with its ordinary meaning; no further construction is necessary," [d. at 3.			

Aniscipation by The Pao '499 Patent DTX-21

Cigim 46 of the '536 Patent	stent The Court's Claim Construction Smith & Nephew's Evidence	Smith & Nephew's Evidence	ArthroCare's Position
An electrosurgical system as		Pao '499 discloses all the limitations of	See above.
in claim 45, wherein		claim 45 as show above.	
orms a	The Court did not construe this	Pao '499 discloses that the outer	ArthroCare did not offer any
portion of the shaft of the	limitation.	electrode 228 (i.e., the return electrode)	rebuttal evidence or dispute
electrosurgical probe.		forms a portion of the probe (shaft)	that Pao '499 met this
		region. Col. 2, lines 58-60, see Figs. 7	limitation at trial.
		and y.	•
		Dr. Taylor's testimony at Tr. 1312.	

Cloim & of the '436 Patent	stone The Court's Claim Construction Smith & Nephew's Evidence	Smith & Nephew's Evidence	ArthroCare's Position
\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\		Pao '499 discloses all the limitations of claim 45 as show above	See above.
the target site is selected from	the target site is selected from The Court did not construe this	Target sites described in this reference	ArthroCare did not offer any
the group consisting	limitation.	include the nose and ears. Col. 9, lines	rebuttal evidence or dispute
essentially of the abdominal.		37-42.	that Pao '499 met this
cavity, thoracic cavity, knee,			limitation at trial.
shoulder, hip, hand, foot,		Dr. Taylor's testimony at Tr. 1312-13.	
elbow, mouth, spine, car,	•		
nose, throat, epidermis and			
dermis of the patient's body.			

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Anticipation by the Manwaring '138 Patent DTX-46

Claim 1 of the '882' Patent	The Court's Claim Construction	Smith & Nephew's Evidence	ArthroCare's Position
1.		Manwaring '138 generally describes	ArthroCare did not offer any
to a target site on a petient		applying RF energy to tissue for	rebuttal evidence or dispute
body structure comprising:		endoscopic procedures. Col. 1, lines 7-9.	that the Manwaring '138
		•	patent met the preamble at
		Dr. Taylor's testimony at Tr. 1314-15	trial.
providing an electrode	"Consistent with the intrinsic	Manwaring '138 discloses a conductor	ArthroCare did not offer any
terminal and a return	evidence of the patents in suit,	34 with a second end 36 (electrode	rebuttal evidence or dispute
electrode electrically coupled	'electrode terminal' means 'one or	terminal) within recessed cylinder	that the Manwaring '138
to a high frequency voltage	more active electrodes." D.L. 353 at	chamber 38 and a first end coupled to the	patent met this limitation at
Source	ri	RF generator. Col. 5, lines 37-43. A	trial.
		return electrode is located on the patient	
	"The court shall apply the ordinary	and connected to the RF generator. Col.	
	definition of the term active	6, lines 38-40.	
	electrode' in the relevant art. The	•	
	term 'active electrode' means 'a	Dr. Taylor's testimony at Tr. 1314-15	
	stimulating electrode applied to	Dr. Manwaring's testimony at Tr. 889-90	
	tissue for stimulation and		
	distinguished from (a return	•	
•	electrodel by having a smaller area		
	of contact, thus affording a higher		
	cummt density " Id		
:	"As contrasted with an active		
	electrode, the term 'return electrode'		
	means 'an electrode having a larger		
	area of contact than an active		
	electrode, thus affording a lower		
	current density." D.I. 353 at 4.		

1 For this analysis only, Smith & Nephew will assume that the Certificate of Correction is valid.

Anticipation by the Manwaring '138 Patent DTX-46

	ŀ	C A M. L Paridance	ArthroCare's Position
Claim 1 of the '882' Patent	The Court's Claim Construction	Smith & Nepnew's Evidence	Author Aid not offer any
1	"Consistent with the ordinary	To the extent this claim can be	יייייייייייייייייייייייייייייייייייייי
positioning the active	Colloboration with the continue of the continu	understand and the Certificate of	rebuttal evidence of dispute
electrode in close proximity	definition, electrically conducting	Charles in found to be walled	that the Manwaring '138 .
to the target site in the	fluid, and electrically conductive	Correction is found to verify	natent met this limitation at
persence of an electrically	fluid' shall be construed to mean	Manwarme 150 mechanes positioning	lei-H
conducting terminal: and	any fluid that facilitates the passage	the active electrode 30 in close proximity	
(of electrical current. Examples of	to the target dissue in the presence of	٠
	electrically conducting fluids are	saline, Col. 6, lines 3-8, 53-57 and 04-	,
	blood and saline." Id. at 3.	68.	
		100000	
	•	Dr. Taylor's testimony at Ir. 1314-15	
		Dr. Manwaring's testimony at Tr. 890-91	
	The Court Ald and construe this	Manwaring '138 discloses applying RF	ArthroCare did not offer any
applying a high frequency		energy to create a spark which vaporizes	rebuttal evidence or dispute
voltage between the electrode	limmon.	the saline within the region 46 adjacent	that the Manwaring '138
terminal and the return		the entire electrode Col 6 lines 50-63:	patent met this limitation at
electrode, the high frequency			Tiel.
voltage being sufficient to		7.1%	
vaporize the fluid in a thin		Te Teulos's testimony at Tr. 1314-15	
layer over at least a portion of		D. Menuming's testimony at Tr. 891-93	
the electrode terminal and to			
induce the discharge of	•		
energy to the target sile in			
contact with the vapor layer.			

Anticipation by the Manwaring '138 Patent DTX-46

		1	>		_	_	 5			<u> </u>	- - - - - - - - - - -				s:	_	Ğ.	<u>e</u>		
ArthroCare's Position	See above.		ArthroCare did not offer any	rebuttal evidence.	However, ArthroCare did	cross-examine Drs. Taylor	and Manwaring with respect	to whether the Manwaring	138 patent explicitly	discloses the production of	photons having a wavelength	in the ultraviolet spectrum	(UV photons). However,	both Drs. agreed that the	production of UV photons is	inherent when sparking	ccurs in an aqueous solution.	Sec, Tr. 1419-20 (Dr. Taylor)	and Tr. 918-19 (Dr.	Manwaring).
Smith & Nephew's Evidence	Manwaring '138 discloses all the	Imitations of Claim I as show above.	Manwaring '138 specifically mentions	sparking during operation. Column 6,	solution, such as saline, results in the	emission of UV photons and other	wavelengths of light.	-	Dr. Taylor's testimony at Tr. 1316	Dr. Manwaring's testimony at Tr. 893-94	and 917-19.			-						
The Court's Claim Construction			The Court did not construe this	limiation.			•		-											
Claim 13 of the '882	The method of claim 1	wherein	at least a portion of the	energy induced is in the form	wavelength in the ultraviolet	spectrum.	•													

Ctalm 54 of the '882	The Court's Claim Construction Smith & Nephew's Evidence	Smith & Nephew's Evidence.	ArthroCare's Position
The method of claims 23 or 48 further comprising		Manwaring '138 discloses all the limitations of Claim 1 and 28 as show above.	See above.
evacuating fluid generated at the target site with a suction interaction of dietal and	evacuating fluid generated at The Court did not construe this the target site with a suction limitation.	Manwaring '138 discloses evacuating fluid generated at the target site using a section human with a distal and adjacent	ArthroCare did not offer any rebuttal evidence.
adjacent the electrode terminal.		the electrode terminal. Col. 7, lines 26-31,	ArthroCare did cross-examine Drs. Taylor and Manwaring

Anticipation by the Manwaring '138 Patent DTX-46

		Contr. & Nanhew's Evidence	ArthroCare's Position
Claim 54 of the '882	The Court's Claim Construction	Sinka & Constant	with respect to whether the
		Dr. Taylor's testimony at Tr. 1316-17 Dr. Manwaring's testimony at Tr. 895- 96; see also 920-21:	Manwaring '138 patent discloses evacuating the fluid generated at the target site.
		Q. Would there be some fluid that was removed from the target site?	However, AritroCare's misleading and irrelevant constions focused on whether
		A. Yes. Fluid would always be there, and the evacuation, whether it is sucking, essentially pulls fluid which is salt laden, electrically conductive, by the electrode. That's the principle.	all the fluid was evacuated (Tr. 1432-33) and whether it was the electrically conducting fluid being evacuated (Tr. 903-05).
		Q. Now, the fluid that is evacuated, would that include fluid that was generated at the target sile?	First, there is no requirement that all the fluid be evacuated from the target site. Second, Dr. Manwaring made it quite
		A. It can.	clear that a mixture of Iluid generated at the target site (e.g. gases) and electrically
		include?	conductive fluid would be evacuated from the target site
		A. Well, heating in the presence of biologic tissue. Let's say one is ablating, which means removing, tumor tissue in the heat. That tissue is vaporized. And	ArthroCare did not rebut Smith & Nephew's prima facte showing of invalidity.
		in that vaportzation is fluid in the form of gas, which quickly mingles with the spinel fluid or the irrigated normal saline.	
		20 It 9 It 11 It was a family	

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Claim 45 of the '536	The Court's Claim Construction	Smith & Nephew's Evidence	ArthroCare's Position
An electrosurgical system for applying electrical energy to a target site on a structure within or on a patient's body, the system comprising:	"The court shall apply the ordinary definition of the term 'system.' The term 'system.' The term 'system' shall be construed to mean 'an assemblage or combination of things or parts forming a unitary whole." D.I. 353 at 5.	Doss '007 describes a bipolar probe, used to apply RF energy to target tissue. See the Abstract; see also col. 1, lines 10-13; col. 2, lines 42-54. All of the components, including the fluid supply, are combined as a unitary whole in the probe.	ArthroCare did not offer any rebuttal evidence or dispute that the Doss '007 patent met the preamble at trial.
	-	Dr. Taylor's testimony at Tr. 1306.	
a high frequency power supply;	The Court did not construe this limitation.	Doss '007 discloses using the electrosurgical device with a radio frequency generator. Col. 3, lines 29-38. A radio frequency generator is a high frequency power supply.	ArthroCare did not offer any rebuttal evidence or dispute that the Doss '007 patent met this limitation at trial.
		Dr. Taylor's testimony at Tr. 1306.	
an electrosurgical probe comprising a staff having a proximal end and a distal end,	"The term 'distal end' shall be construed to mean 'the end situated away from the point of origin or attachment." The term 'proximal end' shall be construed to mean 'the end situated towards the point of origin or attachment."" D.I. 353 at 5.	Doss '007 discloses a housing 70 (probe) including concentric electrodes 72 and 74 separated by insulating member 76 (together making up the shall). The electrodes have a working end (distal end) and a proximal end. Col. 5, lines 27-31. Figure 7 generally shows a distal end and proximal end.	ArthroCare did not offer any rebuttal evidence or dispute that the Doss '007 patent met this limitation at trial.
		Dr. Taylor's testimony at Tr. 1306-07.	

Claim 45 of the '536	The Court's Claim Construction	Smith & Nephew's Evidence	ArthroCare's Position
an electrode terminal	"Consistent with the intrinsic	Doss '007 discloses an central electrode	ArthroCare did not offer any rebuttal evidence or dispute
	'electrode terminal' means 'one or	single active electrode) at the working	that the Doss '007 patent met
	more active electrodes," D.I. 353 at	(distal) end of the shaft. Sec. e.g., col. 5,	this limitation at trial.
	ค่	lines 27-41. Figure 7 shows generally the	
•		central electrode 72 (electrode terminal)	
	The court shall apply the ordinary	of which only a working end (distail end)	
	definition of the term active	is exposed to produce the electric field	
	electrode' in the relevant art. The	102.	
	term active electrode means a		
	sumulating electrode applied to	Dr. 1aylor's testimony at 1r. 150%.	
	tissue for stimulation and		
	electrodel by having a smaller area		
	elections of institute a sussion and		
	current density." Id.		
a connector near the proximal	"The word connect means 'to bind	Doss '007 discloses an operable	ArthroCare did not introduce
end of the shaft electrically	or fasten together; join or unite:	connection between the tubular	any rebuttal evidence.
coupling the electrode	link[,] The word 'connector,' in	electrodes and the RF generator that	
terminal to the electrosurgical	terms of the '536 patent, shall be	electrically couples the electrodes to the	ArthroCare did, however,
power supply:	construed to mean 'a structure that	RF generator. Col. 3, lines 30-34 and	cross-examine Dr. Taylor
	electrically links the electrode	Figs. 7 and 9. Further, since the	with respect to whether the
	terminal to the high frequency	electrodes go through the proximal end,	location of the connector is
	power supply." D.I. 353 at 2.	as seen in Fig. 7, Doss '007 discloses a	explicitly disclosed in the
		connector under the Courts claim	Doss '007 patent. (Tr. at
		construction.	1400).
		Dr. Taylor's testimony at Tr. 1307	However, ArthroCare put
			ionn no evidence which
			would rebut the disclosure in
			Taylor's testimony.

ArthroCare's Position	ArthroCare did not introduce			ply). ArthroCare ato, nowever,		b		_	outer patent caused a tissue effect.						original claim construction,			had a	_	construction, but let	ArthroCare proceed under the	_		electrode?	THE COURT: Well, if you				this definition there has to be	the Doss a difference between the	┪
Smith & Nenhew's Evidence	+	Doss '00/ discloses an ounce circums 74 (return electrode), which is	electrically coupled to the radio-		_			affords a lower current density than the	amaller inner electrode. Thus, outer	electrode 74 satisfies the Court's claim	construction for a return electrode.	-	Tevlor's testimony at Tr. 1307 and	1466 47(amphasis added):	-(On Did you use the Court's definition	of setting electured in determining	whether or not the Doss reference had a			A. Yes.		Q. And what is the critical element of	the Court's definition of when a company of the companying constitutes a return electrode?	4::::::::::::::::::::::::::::::::::::::	A. The critical element is an electrode	having a larger area of contact than an	active electrode, take affording a correct	current density.	Q. And when you reviewed the Doss	patent, did you find such an electrode?
	The Court's Claim Construction	"As contrasted with an active	ciccooc, us sam termi	having a larger area of contact than	an active electrode, thus affording a	former directly density " D.I. 353 at	10WG CALLEN COLLEGE	:		* Symbol 1																			•	-	
•	Claim 45 of the '536	Fi	coupled to the electrosurgical	power supply; and		-													7							·				-	

Anticipation by The Doss '007 Patent DTX-17

Claim 45 of the '536	The Court's Claim Construction	Smith & Nephew's Evidence	ArthroCare's Position
		A Vec The mitter electrode isinet	are saying and your point is
	•	look at the geometry	reference there is no
		4	difference between the two.
			then that is an appropriate
		And just on the basis of plane geometry	like of closs.
		if you assume both electrodes have the	However, counsel never
		same mickness, the outer electrode will have more surface area.	attempted to show there was
	-		no difference, but rather only
		Q. And does that outer electrode meet the Court's definition of a return	effect (Tr. at 1396).
		electrode?	Thus, ArthroCare did not
		A. I believe it does.	rebut Smith & Nephew's
			prima facte showing of
			invalidity.

Chaim 45 of the '536	The Court's Claim Construction	Smith & Nephew's Evidence	ArthroCare's Position
	Monaistent with the prosecution	Doss '007 discloses a tubular central	ArthroCare did not offer any
an electrically conducting	history the nhrace telectrically	electrode 72 with an aperture 84 that	rebuttal evidence or dispute
The supply to uncome	conducting fluid simply shall be	delivers electrically conducting coolant,	that the Doss ,002 patent met
of the terror elle auch that the	construed to mean 'a medical	such as saline, to the target tissue, which	this limitation at trial.
electrically conducting fluid	container that stores electrically	will create a current path between the	
generates a current flow path	conducting fluid." An example of	central electrode 72 and the outer	
between the return electrode	a medical container is an IV bag.	electrode 74. See, col. 5, lines 32-41;	
and the electrode terminal.	An example of electrically	col. 6, lines 1-4; col. 3, line 65 through	
	conducting fluid is isotonic saline."	col. 4, line 7; col. 3, lines 48-54; col. 4,	
•	D.I. 353 at 2.	lines 36-40. "A liquid electrically	•
		conductive coolant is made to flow	
	"Consistent with the ordinary	through or adjacent to at least one of the	
,	definition 'electrically conducting	electrodes onto the comes, then, from	
	Anid and beenically conductive	the comes, through or adjacent to the	
	Child and Chambrid to mean	where electrode." Col. 2, lines 51-55.	
			-
	any fluid that facilitates the	To The last tendiment of Tr 1107.08	
,	passage of electrical current.	Dr. 1 aylor a testimony at 11: 1507-00.	:
	Examples of electrically conducting	-	
	fluids are blood and saline." Id. at		
	ค่		
	Directing or delivering the		
	electrically conductive time to use		-
	target site "shall be construct		
	consistent with its ordinary		
	meaning; no further construction is		
	neversally. In. at 9:		

Claim 46 of the 4536	The Court's Claim Construction	Smith & Nephew's Evidence re: the ArthroCare's Position Doss '007 Patent	ArthroCare's Position
An electrosurgical system as in claim 45, wherein		Doss '007 discloses all the limitations of See above. claim 45 as shown above.	See above.
the return electrode forms a portion of the shaft of the electrosurgical probe.	The Court did not construe this limitation.	Doss '007 discloses a central electrode 72 and an outer electrode 74. Col. 5, lines 27-31. These electrodes, together with the insulating member 76, make up the shaft of the electrosurgical probe Fig. 7. Thus, the outer electrode 74 (return electrode) forms a portion of the shaft.	See discussion above regarding ArthroCare's irrelevant cross-examination of Dr. Taylor with respect to whether the return electrode caused a tissue effect.
		Dr. Taylor's testimony at Tr. 1308.	

Claim 47 of the '536	The Court's Claim Construction	Smith & Nephew's Evidence re: the Doss '007 Patent	ArthroCare's Position
An electrosurgical system as in claim 46 further including		Doss '007 discloses all the limitations of claim 46 as shown above.	See above.
an insulating member oircumscribing the return electrode,	"The court shall apply the ordinary definition of the phrase 'insulating member.' Thus, the phrase 'insulating member shall be construed to mean 'a member which provides a high degree of resistance to the passage of charge." D.I. 353 at 4.	Doss '007 discloses a housing 70 which circumscribes the outer (return) electrode 74. Col. 5, lines 27-31. The housing is generally a plastic material (insulating). Col. 4, lines 15-17. Dr. Taylor's testimony at Tr. 1308-09.	ArthroCare did not offer any rebuttal evidence or dispute that the Doss '007 patent met this limitation at trial.
the return electrode being sufficiently spaced from the electrode terminal to minimize direct contact between the return electrode	The Court did not construe this limitation, although it did construe a similar limitation as follows: "The claim limitation 'the return	Doss '007 shows the outer (return) electrode spaced from the inner electrode (electrode terminal). See, e.g., Fig. 7. "The tips of the electrodes are positionable adjacent and spaced from a	See discussion above regarding ArthroCare's irrelevant cross-examination of Dr. Taylor with respect to whether the return electrode

76.50	The Court's Claim Construction	The County, Claim Construction Smith & Nephew's Evidence re: the	ArthroCare's Position
Civin 4/ of the '350		Doss '007 Patent	
and the patient's tissue.	electrode is not in contact with the body structure' is cleat – the return electrode is not to contact the body at all during the performance of the claimed method." Id. at p. 2 (emphasis in original).	subject comea." Col. 2, lines 50-55. Even if the inner electrode were moved into contact with the tissue 78, the spacing of the outer electrode from the electrode terminal (inner electrode) will prevent it from touching the tissue.	caused a tissue effect.
		Dr. Taylor's testimony at Tr. 1309	

Claim 1 of the '592	The Court's Claim Construction	The Court's Claim Construction Smith & Nephew's Evidence re: the ArthroCare's Fosition Doss '007 Patent	ArthroCare's Position
A method for applying electrical energy to a target site on a body structure on or within a patient's body, the method comprising:		Doss '007 describes a bipolar probe, used to apply RF energy to target tissue. See the Abstract; see also col. 1, lines 10-13; col. 2, lines 42-54.	ArthroCare did not offer any rebuttal evidence or dispute that the Doss '007 patent met the preamble at trial.

Claim 1 of the '592 positioning an electrode terminal into at least close proximity with the target site in the presence of an electrically conductive fluid;	struction nsic. suit, s. one or D.I. 353 at cordinary ive art. The art. The cans 'a	Smith & Nephew's Evidence ret the Doss '007 Patent Doss '007 discloses an inner electrode 72 (electrode terminal) which is an active electrode. Col. 5, lines 27-36. It is positioned over the target tissue in the presence of saline. Col. 3, lines 48-54 and claim 1; see also col. 6, lines 1-4; Fig. 7. Dr. Taylor's testimony at Tr. 1326-27.	ArthroCare's Position ArthroCare did not offer any rebuttal evidence or dispute that the Doss '007 patent met this limitation at trial.
	distinguished from fa return electrode] by having a smaller area of contact, thus affording a higher current density." Id. "Consistent with the ordinary definition, 'electrically conductive fluid' and 'electrically conductive fluid' shall be construed to mean 'any fluid that facilitates the passage of electrical current.' Examples of electrically conducting fluids are blood and saline." Id. at 3.		

		And the second s	
Claim 1 of the '592	The Court's Claim Construction	Smith & Nephew's Evidence re: the Doss '007 Patent	ArthroCare's Position
positioning a return electrode within the electrically conductive fluid such that the return electrode is not in contact with the body structure to generate a current flow path between the electrode terminal and the return electrode; and	"As contrasted with an active electrode, the term 'return electrode' means 'an electrode having a larger area of contact than an active electrode, thus affording a lower current density." D.I. 353 at 4. "The claim limitation 'the return electrode is not in contact with the body structure' is cleat — the return electrode is not to contact the body at all during the performance of the claimed method." [d. at p. 2 (emphasis in original).	Doss '007 discloses an outer electrode 74 (return electrode) in the saline and not in contact with the target tissue. Col. 5, lines 27-38 and 57-58; Fig. 7. Dr. Taylor's testimony at Tr. 1327	See discussion above regarding ArthroCare's irrelevant cross-examination of Dr. Taylor with respect to whether the return electrode caused a tissue effect.
applying a high frequency voltage difference between the electrode terminal and the return electrode such that an electrical current flows from the electrode terminal, ihrough the region of the target site, and to the return electrode through the current flow path.	"[Through the region of the target site] shall be construed consistent with its ordinary meanings no further construction is necessary." [4, at 4.	Doss '007 discloses applying RF energy to the electrodes thereby producing a current that flows from the inner electrode, through the target tissue and then to the outer electrode via the saline. Col. 5, lines 38-41; see also current flow lines in Fig. 7. Dr. Taylor's testimony at Tr. 1328	ArthroCare did not ouer any rebuttal evidence or dispute that the Doss '007 patent met this limitation at trial.
Claim 3 of the '592	The Court's Claim Construction	Smith & Nephew's Evidence re: the	ArthroCare's Position

The Court's Claim Construction Smith & Nephew's Evidence ret the ArthroCare's Fosition Doss '007 Patent
Doss '007 discloses all the limitations of See above.
claim i as shown above.

	Dr. Taylor's testimony at Tr. 1328-29		return electrode
caused a ussue effect.	(col. 5, lines 31-41; Fig. /).	lower current density." D.J. 353 at	electrode terminal and the
whether the return electrode	between the inner and outer electrodes	an active electrode, thus affording a	flow path between the
of Dr. Taylor with respect to	4, line 2) and provides a flow path	having a larger area of contact than	fluid to generate the current
irrelevant cross-examination	target tissue (col. 3, line 65 through col.	electrode' means 'an electrode	of electrically conductive
regarding ArthroCare's	provides electrical conduction to the	electrode, the term 'return	electrode within the volume
See discussion above	Doss discloses that the isotonic saline	"As contrasted with an active	positioning the return
	Dr. Taylor's testimony at Tr. 1328-29	•	
-	lines 31-36; col. 4, lines 19-21.	place under a fluid[.]" D.I. 353 at 4. lines 31-36; col. 4, lines 19-21.	
this limitation at trial.	which acts as a damming device. Col. 5,	nto or	and
that the Doss '007 patent met	The saline is contained by skirt 82,	The term 'immersing' shall be	electrically conductive fluid
rebuttal evidence or dispute	Doss discloses pumping isotonic salme to the target site. Col. 3, lines 48-54.	"The court shall apply the ordinary definition of the term 'immersing."	immersing the target site
	Doss '007 Patent		
ArthroCare's Position	Smith & Nephew's Evidence re: the	The Court's Claim Construction	Claim 3 of the '592

		ı	
Claim 4 of the '592	The Court's Claim Construction	The Court's Claim Construction Smith & Nephew's Evidence re: the Doss '007 Patent	ArthroCare's Position
The method of claim 1 further comprising		Doss '007 Patent discloses all the limitations of claim 1 as shown above.	See above.
delivering the electrically conductive fluid to the target site.	"This plurase shall be construed consistent with its ordinary meaning; no further construction is	Doss '007 discloses delivering saline to the target site through the inner electrode. Col. 3, lines 48-54.	ArthroCare did not offer any rebuttal evidence or dispute that the Doss '007 patent met this limitation at trial.
		Dr. Taylor's testimony at Tr. 1329.	

Claim 11 of the '592	The Court's Claim Construction	Smith & Nephew's Evidence re: the	ArthroCare's Position
		Doss '007 Patent	
The method of claim I		Doss '007 Patent discloses all the limitations of claim 1 as shown above.	See above.
the electrically conductive fluid comprises isotonic	The Court did not construe this limitation.	Doss '007 discloses delivering isotonic saline, Col. 3, lines 65-68.	ArthroCare did not offer any rebuttal evidence or dispute the the Poss 1007 patent mel
saline.		Dr. Taylor's testimony at Tr. 1329.	this limitation at trial.
			Destelon
Claim 21 of the '592	The Court's Claim Construction	Smith & Nephew's Evidence re: the Doss '007 Patent	Ararocare's rosinou
The method of claim 1		Doss '007 discloses all the limitations of claim I as shown above.	See above.
wherein	HISON to 1400 Volte Peak to Peak!	Doss '007 discloses the use of voltages	ArthroCare did not introduce
the voltage is in the range from 500 to 1400 volts peak	shall be construed consistent with	between about 20 and 200 volts RMS.	any rebuttal evidence.
to peak.	its ordinary meaning; no further	is not specified but is almost certainly a	ArthroCare did, however,
	construction is increased;	sine wave. Hence, Doss '007 discloses	cross-examine Dr. Taylor
•	•	the use of a voltage range from about 56	with respect to whether Doss
		to 566 voits peak to peak.	wave. (Tr. at 1402).
		Dr. Taylor's testimony at Tr. 1330	Tombib are Downer A second
			rebut Smith & Nephew's
			prima facte showing, nor did
-			to overcome Dr. 1 aylor s
			explicitly disclosed, the
	•		waveform was inherently
	-		disclosed (Tr. at 1402):

Anticipation by The Doss '007 Patent DIX-17

A[T]o my knowledge, there are no commercially-available square wave generators.	Claim 21 of the '592	The Court's Cialm Construction	The Court's Claim Construction Smith & Nephew's Evidence re: the ArthroCare's Position Doss '007 Patent	ArthroCare's Position
				A[T]o my knowledge, there are no commercially-available square wave generators.

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Anticloation by The Slager Article DTX-65

Artliro Care's Position	ArthroCare did not introduce any rebuttal evidence.	ArthroCare did, however, cross-examine Dr. Taylor	with respect to whether the Slager Article disclosed applying energy to a patient	body structure because it describes in vitro tests.	However, ArthroCare's apparent position was	undercut by Philip Eggers, one of the inventors of the	patents-in-suit, who testified that the inventions were	in-vitro experiments on chicken parts in bowls of saline (Tr. at 295).	Thus, ArthroCare did not rebut Smith & Nephew's prima facie showing of invalidity.
Smith & Nephew's Evidence	The Slager Article generally discloses applying HF energy to a target site (the heart). Specifically, the Slager Article	discloses in-vitro tests on acetic tissue in a lab dish. p. 1383.	Dr. Taylor's testimony at Tr. 1318.	:			-		
The Court's Claim Construction						:		· · · · · ·	· · · · · · · · · · · · · · · · · · ·
Claim 1 of the '882' Patent	A method for applying energy to a target site on a patient	· Purer di monte como							

Por this analysis only, Smith & Nephew will assume the Certificate of Correction is valid.

Anticipation by The Slaver Article DTX-65

	t	The Cartie Lands Desidones	ArrhroCare's Position
Claim 1 of the '882' Patent	tion	Smith & Nephew's Evidence	ArthroCare did not offer any
providing an electrode	"Consistent with the intrinsic	The spark electrode in Slager is all	rebuttal evidence or dispute
terminal and	evidence of the patents in suit,	electrode. p. 1383.	that the Slager Article met
	more active electrodes." D.I. 353 at	Dr. Taylor's testimony at Tr. 1318.	this limitation at that
	ż		
	"The court shall apply the ordinary		
	definition of the term active		
	term 'active electrode' means 'a		
	stimulating electrode applied to		
	tissue for stimulation and	•	
	distinguished from (a return		
	of contact, thus affording a higher		
	current density." Id.		
		Organ displaces a return electrode	ArthroCare did not offer any
a return electrode electrically	"As contrasted with an active	electrically counied to an HF voltage	rebuttal evidence or dispute
coupled to a high frequency	electrode, the term return electrode	source, p. 1383.	that the Slager Article met
voltage source;	means an electrone manife a mage		this limitation at trial.
	electrode, thus affording a lower	Dr. Taylor's testimony at Tr. 1318.	
	current density." D.I. 353 at 4.		A -then Come did not offer any
positioning the active	"Consistent with the ordinary	The spark (active) electrode in Singer is	rebural evidence or dispute
electrode in close proximity	definition, electrically conducting	confidence to the measure of salme, which	that the Slager Article met
to the target site in the	fluid, and electrically conductive	to an electrically conductive fluid. p.	this limitation at trial.
presence of an electrically	fluid' shall be construed to mean	1303	
conducting terminal; and	any fluid that facilitates the passage		
	of electrical current. Examples of	Dr. Taylor's testimony at Tr. 1318-19.	
	electrically conducting numbers		
	DIODE END SHIRTS NO. 45.		

Anticipation by The Singer Article DTX-65

		Claim 1 of the 1882. Patent 1 the Court's Claim Construction Smith & Inchiem's Evidence	
applying a high frequency	The Court did not construe this	A HP voltage is applied between the	ArthroCare did not offer any
ode	limitation.	spark electrode (electrode terminal) and	rebuttal evidence or dispute
terminal and the return		return electrode, resulting in the	that the Slager Article met
electrode, the high frequency		formation of bubbles and a steam layer	this limitation at trial.
voltage being sufficient to		over the spark electrode, discharging	
vaporize the fluid in a thin		energy to the target site in contact with	
layer over at least a portion of		the vapor layer. pp. 1383-84, Fig. 4.	:
the electrode terminal and to			
induce the discharge of		Dr. Taylor's testimony at Tr. 1319.	
energy to the target site in			
contact with the vapor layer.			

Claim 13 of the '882	The Court's Claim Construction	Smith & Nephew's Evidence	ArthroCare's Position
The method of claim 1		The Slager Article discloses all the	See above.
wherein		limitations of Claim 1 as show above.	
at least a portion of the	The Court did not construe this	The Slager Article specifically mentions	ArthroCare did not introduce
energy induced is in the form	limitation.	sparking during operation. pp. 1382-85.	any rebuttal evidence.
of photons having a	•	This inherently results in the emission of	
wavelength in the ultraviolet		UV and other wavelengths of light.	ArthroCare did, however,
mechin			cross-examine Dr. Taylor
		Dr. Taylor's testimony at Tr. 1319; see	with respect to whether the
		also Tr. 1419-20 (emphasis added):	Slager Article explicitly
•			disclosed the production of
		O. So just from seeing a spark, just	UV photons.
		from seeing that flash of light with the	
		naked eye, you can't tell whether or not	However, ArthroCare
		there is ultraviolet light in there or	produced no evidence to rebut
		whether there isn't. True?	Dr. Taylor's testimony that
		•	the production of UV photons
	•	A. That's true, except you can't have a	is inherent in the methods
		spark in aqueous solution without the	disclosed in the Slager
	•	UV Ught.	Article. Thus, ArthroCare did
		•	not rebut smith & Nephew's

Anticipation by The Slager Article DTX-65

ArthroCare's Position	prima facte showing of	invalidity.	
Smith & Nonhew's Evidence		Q. So you didn't do any tests and you didn't look at the literature; correct?	A. Right. One has to realize, though, that if you have a spark in an aqueous solution, especially a sodium chloride aqueous solution, that you will generate UV photons because of the transition of the hydroxyl lon. You will also generate what we would consider to be orange, yellowish-orange light, 580 nanoneters, because of the sodium ion transition. That is college chemistry.
Smith & Nephew's Evidence	The Court's Civin Construction		
	Claim 13 of the '882		

ArthroCare's Position	0.01000	See above.	ArthroCare did not offer any	utal evidence or dispute	that the Slager Article met	this limitation at trial.	•
Til O Man Lands Duidence	Smith & Nepnew's Evidence	The Slager Article discloses all the	limitations of Citating Las significant	the Sigger Audie uses a till voluse of	CONTRACTOR OF THE CONTRACTOR O	Dr. Taylor's testimony at Tr. 1320.	
	The Court's Claim Construction Smith & Nepnew's Evidence		1	did not construe this			
-	Chaim 17 of the 1882		wherein	the high frequency voltage is	at least 200 volts peak to	peak.	

ArthroCare's Position See above.	
The Court's Claim Construction Smith & Nephew's Evidence The Slager Article discloses all the limitations of claims 1 and 28 as show	above.
The Court's Claim Constructi	
Claim 54 of the '882 The method of claims 23 or	48 lumber comprising

Anticipation by The Slager Article DTX-65

uction limitation. uction limitation. uction limitation. end bubbles generated at the target site. p. 1386. Dr. Taylor's testimony at Tr. 1320.	Claim 54 of the '882	The Court's Claim Construction	Smith & Nephew's Evidence	ArthroCare's Position
bubbles generated at the target site. p. 1386. Dr. Taylor's testimony at Tr. 1320.	nerated at a suction	The Court did not construe this imitation.	The Slager Article teaches that a suction technique may be used to remove	ArthroCare did not introduce any rebuttal evidence.
Dr. Taylor's testimony at Tr. 1320.	tal end xde		bubbles generated at the target site. p. 1386.	ArthroCare did cross-examine
However, ArthroCare provided no evidence to rebut the evacuation by a suction lumen adjacent the electrode terminal is inherently disclosed. Thus, ArthroCare failed to rebut Smith & Nephew's prima factoring in the succession of the control of the			Dr. Taylor's testimony at Tr. 1320.	Dr. Taylor with respect to whether the Slager Article explicitly discloses a specific
However, AntwoCare provided no evidence to rebu Dr. Taylor's testimony that the evacuation by a suction lumen adjacent the electrode terminal is inherently disclosed. Thus, ArthroCare failed to rebut Smith & Nephew's prima facte	•			suction tectunique.
Dr. Taylor's testimony that the evacuation by a suction lunen adjacent the electrode terminal is inherently disclosed. Thus, ArthroCare failed to rebut Smith & Nephew's prina facile		-		provided no evidence to rebut
lunen adjacent the electrode terminal is inherently disclosed. Thus, ArthroCare failed to rebut Smith & Nephew's prima facle				Dr. Taylor's testimony that
terminal is inherently disclosed. Thus, ArthroCare failed to rebut Smith & Nephew's prima facle				lumen adjacent the electrode
failed to rebut Smith & Nephew's prima facte			•	terminal is inherently disclosed. Thus, ArthroCare
Nephew's prima facie				failed to rebut Smith &
				Nephew's prima facie

C 42 . CAL. 6604	The Cond's Claim Construction Smith & Nenhew's Evidence	Smith & Nephew's Evidence	ArthroCare's Position
	TARCHAR STORY OF THE STORY AND STORY		Can discussion above
A mestand for sombring		The Slager Article generally describes	ר אכני סואיחאוסיי שהסגני
Survive for selection		Transfer of the Contract of th	- Anna Alina ArthroCare's cross-
electrical energy to a target	-	application of ingn frequency current to legarding transfer	Ickaiding Anna Caro
		manufas tienne (tareed eite)	examination of Dr. Laylor
site on a body structure on or		· · · · · · · · · · · · · · · · · · ·	
within a nationt's body the			With respect to in-vitto tests.
withing ponents of the last			
method comprising:			

Anticipation by The Slaver Article DTX-65

		S. ut P. Nanhambe Evidence	ArthroCare's Position
Claim 23 of the '592	The Court's Claim Construction	Smith & Ideputer a Evincación in Claper is	ArrhroCare did not offer any
contacting an active electrode	"Consistent with the intrinsic	I he spark (active) electrons in classics of contacted to the target site (arterial	rebuttal evidence or dispute
with the body structure in the	evidence of the patents in suit.	plague) in the presence of saline, which	that the Slager Article met
presence of an electrically conductive fluid;	more active electrodes," D.I. 353 at	is an electrically conductive fluid. p.	this limitation at their
	m		
	"The court shall apply the ordinary	Dr. Taylor's testimony at Tr. 1331.	
	definition of the term active		
•	electrode' in the relevant art. The		
	term 'active electrode' means 'a		
	stimulating electrode applied to		
	tissue for stimulation and		
	distinguished from [a return	•	
	electrode] by having a smaller area		
	of contact, thus affording a higher		
	current density." Id.		
	Wenting the ordinary		
	definition, 'electrically conducting		
	fluid' and 'electrically conductive		
	fluid' shall be construed to mean		
	any fluid that facilitates the passage		
	of electrical current. Examples of		
	electrically conducting fluids are		
	blood and saline." Id. at 3.		

Anticipation by The Slager Article DTX-65

Claim 23 of the '592	The Court's Claim Construction	Smith & Nephew's Evidence	ArthroCare's Position
spacing a return electrode	1	The return electrode in Slager is	ArthroCare did not introduce
away from the body structure	electrode, the term 'return electrode'	positioned within saline, which is an	any rebuttal evidence.
in the presence of the	means 'an electrode having a larger	electrically conductive fluid. p. 1383-84.	
electrically conductive fluid;	area of contact than an active	The aortic segment is disclosed as being	Instead, ArthroCare asked
and	electrode, thus affording a lower	approximately 4 x 7 cm in size. P. 1382.	misleading and irrelevant
	current density." D.I. 353 at 4.	The distance between the active and	questions regarding the in-
	•	return "electrodes is varied from 2 to 10	vivo test, which is a different
	"The claim limitation 'the return	cm." P. 1383. Thus, at least when the	test in the article on which it
	electrode is not in contact with the	active and return electrodes are 7 to 10	knew Dr. Taylor did not rely.
	body structure' is clear - the return	cm apart, the return electrode cannot be	(Tr. at 1414-18). Thus,
	electrode is not to contact the body	touching the aortic segment (body	ArthroCare did not rebut
	at all during the performance of	structure). Thus, the Slager Article	Smith & Nephew's prima
	the claimed method." Id. at p. 2	explicitly discloses this limitation.	facte showing of invalidity.
÷	(emphasis in original).	•	
		Dr. Taylor's testimony at Tr. 1331	
applying a high frequency	The Court did not construe this	A HF voltage is applied between the	ArthroCare did not offer any
voltage difference between	limitation.	spark electrode (electrode terminal) and	rebuttal evidence or dispute
the active electrode and the		return electrode, resulting in the flow of	that the Slager Article met
return electrode such that an		an electric current between them and	this limitation at trial.
electrical current flows from		through the electrically conductive fluid.	
the active electrode, through		pp. 1383-84.	
the electrically conductive			
fluid, and to the return		Dr. Taylor's testimony at Tr. 1332.	
electrode.			

Claim 26 of the *592	The Court's Claim Construction	Smith & Nephew's Evidence	ArthroCare's Position
The method of claim 23	•	Inc Singer Article disclosed all the	See above.
further comprising		limitations of claim 23 as show above.	

Anticipation by The Slager Article DTX-65

,		C O Mi. L le Duidonce	ArthroCare's Position
Claim 26 of the '592	The Court's Claim Construction	Smith & Nepnew's Evincing	ArthroCare did not offer any
immersing the target site	"The court shall apply the ordinary	The target site is indirected in the site.	rebuttal evidence or dispute
within a volume of the	definition of the term 'immersing.	Which is an electrodist concurred the concurred the concurred to the concurrence to the concurred to the con	that the Slager Article met
electrically conductive fluid	The term 'immersing' shall be	p. 1707	this limitation at trial.
and	construed to mean 'to plunge into or construed to mean 'to plunge into Taylor's testimony at Tr. 1332	Dr Taylor's testimony at Tr. 1332	
	place under a fluidi.	The return electrode in Slager is	ArthroCare did not offer any
positioning the return	"As contrasted with an active		rebuttal evidence or dispute
electrode within the volume	electrode, the term return electrode		that the Slager Article met
of electrically conductive	means an electrode naving a target	The aortic segment is disclosed as being	this limitation at trial.
fluid to generate a current	area of contact than an active	annoximately 4 x 7 cm in size. P. 1382.	
flow path between the active	electrode, thus attording a lower	The distance between the active and	
electrode and the return	current density." D.1. 353 at 4.	mhm "electrodes is varied from 2 to 10	
electrode.		m " p 1181 Thus at least when the	
		City and return about offer are 7 to 10	
٠		active and remain the second and second	
	•	cm apart, the return electrode cannot be	
		touching the aortic segment (body	
		structure). Thus, the Slager Article	
	•	and the discloses this limitation.	
		explicing discloses and minimum	
		T. T. dan't testimony at Tr. 1332.	
		Dr. 1aylor a testiliony at 111 100-	

			Author Care's Position
	The Court's Claim Construction Smith & Nephew's Evidence	Smith & Nephew's Evidence	Armiocarc
Ī		The Slager Article discloses all the	See Boove.
The method of claim 23		limitations of claim 23 as show above.	
in the commising		or a language immension	ArthroCare did not offer any
ricelly	"This phrase shall be construed	The Mager Article discusses minimisering	reputtal evidence or dispute
100	consistent with its ordinary	the target site in same. P. 1202.	the the Cloude Article met
	si mismi ao farther construction is		ייייי בייייייייייייייייייייייייייייייי
		The Taylor's testimony at Tr. 1333.	this limitation at trial.
	necessary. U.I. 333 8t 3.		

See above.		
Smith & Nephew's Evidence The Shager Article discloses all the	tations of claim 1 as show above.	
'592 The Court's Caim Construction Smith & Nephew's Evidence The Sharer Article discloses all the	of claim 23 limitations of claim 1 as show above.	
Claim 32 of the '592 Th	The method of claim 23 wherein	

Anticipation by The Slager Article DTX-65

Claim 32 of the '592	The Court's Claim Construction Smith & Nephew's Evidence	Smith & Nephew's Evidence	ArthroCare's Position
the electrically conductive	The Court did not construe this	mentions	ArthroCare did not offer any
fluid comprises isotonic	limitation.	using 0.9% (isotonic) saline (p. 1383) as	_
saline.		the conducting fluid.	that the Slager Article met
		•	this limitation at trial.
		Dr. Taylor's testimony at Tr. 1333.	
Claim 42 of the '592	The Court's Claim Construction Smith & Nephew's Evidence	Smith & Nephew's Evidence	ArthroCare's Position
The method of claim 23	•	The Slager Article discloses all the	See above.
		limitations of claim 22 as about about	

Claim 42 of the '592	The Court's Cialm Construction Smith & Nephew's Evidence	Smith & Nephew's Evidence	ArthroCare's Position
The method of claim 23		The Slager Article discloses all the	See above.
	WEOM of JAM Valle Bank to Bank	Clear menifically disoloses the use of a	ArthroCare did not offer any
nic sombe is in nic tanke	ביי וייי וייי וייי איני וייי וייי וייי וי	משפני פורכיוויפוול מופרים יווי מיירים	
from 500 to 1400 volts peak	shall be construed consistent with its	shall be construed consistent with its voltage of 1200 volta peak to peak	rebuttal evidence or dispute
to peak.	ordinary meaning; no further	(1383).	that the Slager Article met
•	construction is necessary." D.L. 353	-	this limitation at trial.
	214.	Dr. Taylor's testimony at Tr. 1333.	

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Anticipation by The Roos '198 Patent . DTX-11

Claim 45 of the '536 Patent	The Court's Claim Construction	Smith & Nephew's Evidence	ArthroCare's Position
An electrosurgical system for applying electrical energy to a target site on a structure within or on a patient's body, the system comprising:	'The court shall apply the ordinary definition of the term 'system.' The term 'system' shall be construed to mean 'an assemblage or combination of things or parts forming a unitary whole." D.I. 353 at 5.	The abstract of Roos '198 generally describes that the Roos invention is an electrosurgical device used to separate or coagulate tissue in a patient. See also, col. I, lines I-22. All of the components, including the fluid supply, are combined as a unitary whole in the device.	ArthroCare did not offer any rebuttal evidence or dispute that the Roos '198 patent met the preamble at trial.
		Dr. Taylor's testimony at Tr. 1301.	
a high frequency power supply;	The Court did not construe this limitation.	Roos '198 discloses a high frequency generator throughout. See, e.g., Claim 1 at col. 7, lines 51-53; col. 7, lines 5-7; and col. 1, lines 5-17.	ArthroCare did not offer any rebuttal evidence or dispute that the Roos '198 patent met this limitation at trial.
		Dr. Taylor's testimony at Tr. at 1302.	
an electrosurgical probe comprising a shaft having a proximal end and a distal end,	"The term 'distal end' shall be construed to mean 'the end situated away from the point of origin or attachment.' The term 'proximal end' shall be construed to mean 'the end situated towards the point of origin or attachment."" D.I. 353 at 5.	Roos '198 discloses a shaft (endoscope) having a front end (distal end) and a rear portion (proximal end). See col. 6, lines 61-68. See also Fig. 7 and 8, which generally shows a distal end. Dr. Taylor's testimony at Tr. at 1302.	ArthroCare did not offer any rebuttal evidence or dispute that the Roos 198 patent met this limitation at trial.

Anticipation by The Roos 198 Patent DIX-11

	The County Columnian Construction	Smith & Nephew's Evidence	ArthroCare's Position
Claim 45 of the '330 Patent	Ind Courts Charle Court access		AnthroCare did not offer any
an electrode terminal disposed near the distal end, and	"Consistent with the intrinsic evidence of the patents in suit, "electrode terminal" means 'one or more active electrodes." D.I. 353 at 3. "The court shall apply the ordinary definition of the term "active electrode" in the relevant art. The term "active electrode" means "a stimulating electrode applied to tissue for stimulation and distinguished from [a return electrode] by having a smaller area of contact, thus affording a higher	Rocs '198 discloses a treament electrode, consisting of a single active electrode, projecting from the front (distal) end of the endoscope (shaft). See, e.g., col. 6, lines 67-68; Claim I at col. 7, lines 47-48. See also Fig. 7, which generally shows a treatment electrode (12) at the distal end of the endoscope (13). Dr. Taylor's testimony at Tr. at 1302.	rebuttal evidence or dispute that the Roos '198 patent met this limitation at trial.
a connector near the proximal end of the shaft electrically coupling the electrode terminal to the electrosurgical power supply;	"The word connect means 'to bind or fasten together; join or unite; link[.]" The word 'connector,' in terms of the '536 patent, shall be construed to mean 'a structure that electrically links the electrode terminal to the high frequency power supply."" D.I. 353 at 2.	Roos '198 discloses a connector near the proximal end of the endoscope (shaft). "In the present embodiment, two leads 16 pass outwards from the cylindrical neutral electrode 11, which at 20 are combined to form a single cable, leading to the rear end of the endoscope 13. The neutral electrode 11 is connected via a further insulated cable 14 to the high frequency generator" Col. 7, lines 1-7 (emphasis added). Figure 7 and claim 1 further disclose a connector—"Insulated cable means for connecting said treatment electrode to one pole of a high-frequency generator" Claim 1 at col.	ArthroCare did not introduce any rebuttal evidence. This was not surprising, since in the pretrial proceedings, ArthroCare's expert, Dr. Goldberg, had already admitted that the Roos '198 patent discloses a connector near the proximal end of the shaft. (Goldberg Dep. at 521-22, Exhibit). ArthroCare did, however, attempt to cross-examine Dr. Tavlor with respect to

Anticipation by The Roos '198 Patent DTX-11

ArthroCare's Position	whether the location of the connector is explicitly disclosed in the Roos '198 patent (Tr. at 1371-72): A. Well, there is a	Connector. 1 nere nas to oc. Q. I am not asking you that question. I am soying that you have been able to review	the '198 patent and you have been able to discern some description in there of the location of the connector. Not that there is one. But the specific location of it; right?	A. There is not a specific reference to a location of the connector.	However, ArthroCare did not rebut Smith & Nephew's prima facie showing, as Dr. Taylor explained the location of the connector was inherently disclosed (Tr. at 1370-72):	A. You do realize that all resectoscopes have
Smith & Nephew's Evidence	7, lines 50-53; see also Claim 15, col. 8, lines 49-52 (which discloses a connector separate from the cable means). Also Figs. 4-6 show the connector schematically.	Dr. Taylor's testimony at 1r. at 1302-03.	-			
The Court's Claim Construction		-				-
Claim 45 of the '536 Patent						

Anticipation by The Ross '198 Patent DTX-11

			A theo Care's Position
\vdash	The Court's Claim Construction	Smith & Nephew's Evidence	
Claim 45 of the '536 Fatent	1		connectors at the back end of the resectoscope.
	-		A. There is nothing in the 198 patent that says it explicitly. But there are no resectoscopes on the market that don't have a connector at the end, on the back of the resectoscope.
		a postorio	ArthroCare did not offer any
a return electrode electrically coupled to the electrosurgical power supply; and	"As contrasted with an active electrode, the term 'return electrode' means 'an electrode having a larger area of contact than an active electrode, thus affording a lower current density." D.I. 353 at	Roos '198 discloses a remm encurous electrically coupled to the high frequency generator (power supply) . See, e.g., Claim 1 at col., 7, lines 52-53; col. 7, lines 5-7. See also Figs. 4-6, 8 and 9.	rebuttal evidence or dispute that the Roos 198 patent met this limitation at trial.
	4	Dr. Taylor's testimony at Tr. at 1303.	
an electrically conducting fluid supply for directing electrically conducting fluid to the target site such that the electrically conducting fluid generates a current flow path between the return electrode and the electrode ferminal.	"Consistent with the prosecution history, the pluase 'electrically conducting fluid supply' shall be construed to mean 'a medical container that stores electrically conducting fluid An example of a medical container is an IV bag. An example of electrically conducting fluid is isotonic saline." D.I. 353 at 2.		ArthroCare did not offer any rebuttal evidence. ArthroCare did crossexamine Dr. Taylor with respect to whether the Roos '198 patent explicitly discloses electrically conductive fluid. However, ArthroCare did not provide any evidence to rebut Smith
			•

Anticipation by The Roos '198 Patent DTX-11

		 			_ 	
ArthroCare's Position	& Nephew's prima facie showing of invalidity.					
Smith & Nephew's Evidence	52-56. Liquid to provide electrical conductance clearly fits the Court's claim construction of "fluid that facilitates the passage of electrical current." Dr. Taylor's testimony at Tr. at 1303-04 (emphasis added):	Q. Have you done an element-by- element comparison of the teachings of the Roos '198 with the claims of the '536 patent? A. Yes, I have.	Q. Have you prepared some slides to illustrate that?	A. Yes, I have	It also requires an electrically conducting fluid supply, directed to the target site and generating current, flow path between the active and return electrode. That is diagrammarically shown here in Figures 7 and 8 and also specifically called out in Claim 1, basically the last line in Claim 1, that element is satisfied.	Q. Just to pause on this one for a morrient, that language that is ounced
The Court's Claim Construction	"Consistent with the ordinary definition, 'efectrically conducting fluid' and 'electrically conductive fluid' shall be construed to mean 'any fluid that facilitates the passage of electrical current." Examples of electrically conducting fluids are blood and saline." Id. at 3.	Directing or delivering the electrically conductive fluid to the target site "shall be construed consistent with its ordinary meaning no further construction is	inconsily. In the J.			
Claim 45 of the '536 Patent						

Anticipation by The Roos '198 Patent DIX-11

			A ethroCare's Position
frated Afthe 1876 Patent	nt The Court's Claim Construction Smith & Nephew's Evidence	Smith & Nephew's Evidence	Attatoonis as a second
		below the drawing comes from Claim 1 of the Roos '198 patent?	٠
		A. That's correct.	
		Q. That is where you found support for the electrically conducting fluid limitation?	
		A. Yes,	

ArthroCare's Position	See above.	ArthroCare did not offer any rebuttal evidence or dispute that the Roos '198 patent met this limitation at trial.	
Smith & Nanhaw's Evidence	Roos '198 discloses all the limitations of See above.	ciaim 43 as since above. In the device of Figures 7 and 8 of Roos 1198, neutral electrode 11 (the "return electrode") forms a portion of the endoscope, which is the shaft of the probe.	Dr. Taylor's testimony at Tr. at 1304.
	Claim 46 of the '536 Patent The Court's Claim Construction Roos '198 discloses all the limitat	The Court did not construe this limitation.	
	Claim 46 of the '536 Patent	in claim 45, wherein the return electrode forms a portion of the shaft of the electrosurgical probe.	

	7	
See above.		•
imith & Nephew's Evidence loos '198 discloses all the limitations of	ristem as	-
Claim 47 of the 4336 Patent The Court's Claim Construction Smith & Nephew's Evidence Roos '198 discloses all the limitation		
Claim 47 of the '536 Patent	An electrosurgical system as	in claim 46 nuther including

Anticipation by The Roos '198 Patent DTX-11

Claim 47 of the told Batent	Claim 17 of the 1836 Batent The Court's Claim Construction	Smith & Nephew's Evidence	ArthroCare's Position
CIALLI 47 01 tue 250 A Atent	orthe court shall emply the ordinary	Figures 7 and 8 show an insulating	ArrhroCare did not offer any
an insulating member	The court site is the court of		rehuttal evidence or dispute
circumscribing the return	definition of the purase insulang	THE HOLD WILLIAM OF THE STATE O	terrando de la companya de la compan
electrode.	member. Thus, the phrase	return electrode at the front of the	that the root 150 parent neces
	'insulating member' shall be	resectoscope. Col. 7, lines 8-16.	this limitation at trial.
	construed to mean 'a member which		
	nrovides a high degree of resistance	Dr. Taylor's testimony at Tr. at 1304.	
	to the nassage of charge." D.I. 353	·	
			-
the metal absorbed being	The Court did not construe this	The return electrode disclosed is spaced	ArthroCare did not offer any
	limitation although it did constructs	away from the electrode terminal and	rebuttal evidence or dispute
sufficiently spaceu from the	Illinging, amongs is old voice.	At whether the fact that the same and	that the Pose 1198 natent met
electrode terminal to	similar Emitation as follows:	separated by the insulating memoring.	list alt 1000 170 parent mer
minimize direct contact		See, e.g., Figs. 7 and 8. Thus, the return	this limitation at trial.
	with a claim limitation the return	is sufficiently spaced to minimize contact	
מכנאכשו ווער וכוותוו בוכניו חסב	The Committee and the same		
and the patient's tissue.	electrode is not in contact with the	between the return electrode and the	
	body structure' is cleat - the return	patient's tissue.	
	electrode is not to contact the body	-	
	at all during the performance of	Dr. Taylor's testimony at Tr. at 1304-05.	•
-	the claimed method." Id. at p. 2		,
	(emphasis in original).		
	The state of the s		

|--|--|--|

Anticipation by The Roos '198 Patent DTX-11

Claim 56 of the '536	The Court's Claim Construction	Smith & Nephew's Evidence re: the Roos '198 Patent	ArthroCare's Position
the target site is selected from	the target site is selected from The Court did not construe this	The target sites of the electrosurgical	ArthroCare did not offer any
the group consisting	limitation.	system described in Roos 198 are the	rebuttal evidence or dispute
essentially of the abdominal		prostate or bladder, which are in the	that the Roos 196 patent like
cavity, thoracic cavity, knee,		abdominal cavity. See Col. 1, lines 10-	this innitation at that
shoulder, hip, hand, foot,		22.	
elbow, mouth, spine, car,	٠	1200	
nose, throat, epidermis and		Dr. 1aylor's teamnony at 11. at 1505.	
dermis of the patient's body.			

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Anticipation by The Elsässer/Roos Article DTX-59A and 59B

Claim 45 of the '536 Patent An electrosurgical system for applying electrical energy to a target sile on a structure within or on a patient's body, the system comprising:	Claim 45 of the '536 Patent The Court's Claim Construction An electrosurgical system for "The court shall apply the ordinary applying electrical energy to a definition of the term 'system.' The term' system' shall be construed to term 'system' shall be construed to mean 'an assemblage or combination of things or parts forming a unitary whole." D.I. 353 at 5.	Smith & Nephew's Evidence The Elsässer and Roos Article generally describes an electrosurgical device (i.e. resectoscope) which applies high frequency current to tissue (a target site) for electroresections. See p. 5 of translation. All of the components, including the fluid supply, are combined as a unitary whole in the device.	ArthroCare's Fostion ArthroCare did not offer any rebuttal evidence or dispute that the Elsasser/Roos Article met the preamble at trial.
a high frequency power supply;	The Court did not construc this limitation.	Dr. Taylor's testimony at Tr. 1295-96. The Elsisser and Roos Article discloses a high frequency power supply. See p. 5 of translation.	ArthroCare did not offer any rebuttal evidence or dispute that the Elstlsser/Roos Article met this limitation at trial.
an electrosurgical probe comprising a shaft having a proximal end and a distal end,		Dr. Taylor's testimolity at the Elstisser and Roos Article discloses a resectoscope (probe) shaft having a proximal end and a distal end. See p. 5 of translation and Figs. 8 and 9.	ArthroCare did not offer any rebuttal evidence or dispute that the Elsasser/Roos Article met this limitation at trial.
	end' shall be construed to mean 'the end situated towards the point of origin or attachment," D.I. 353 at 5.	Dr. Taylor's testimony at Tr. 1297-98.	

Anticipation by The Elsässer/Roos Article DTX-59A and 59B

Claim 45 of the '536 Patent	The Court's Claim Construction	Smith & Nephew's Evidence	ArthroCare's Position
	"Consistent with the intrinsic	The Elsasser and Roos Article discloses	ArthroCare did not offer any
disposed near the distal end.	evidence of the patents in suit.	an electrode terminal consisting of a	rebuttal evidence or dispute
	'electrode terminal' means 'one or	single active electrode a cutting loop	that the Elsasser/Roos Article
	more active electrodes." D.I. 353 at	located at the distal end of the	met this limitation at trial.
-	ň	resectoscope (shaft). See p. 5 of	,
٠		translation and Figs. 8 and 9.	
	"The court shall apply the ordinary		
	definition of the term 'active	Dr. Taylor's testimony at Tr. 1298.	
	electrode' in the relevant art. The		
	term 'active electrode' means 'a		
	stimulating electrode applied to		
	tissue for stimulation and		
,	distinguished from [a return		
	electrode) by having a smaller area		
	of contact, thus affording a higher		
	current density." Id.		
a connector near the proximal		The Elsässer and Roos Article clearly	ArthroCare did not offer any
end of the shaft electrically	_	discloses a connector near the proximal	rebuttal evidence or dispute
coupling the electrode		end of the resectoscope (shaft)	that the Elsasser/Roos Article
terminal to the electrosurgical	-	electrically linking the cutting loop	met this limitation at trial.
power supply:	construed to mean 'a structure that	(electrode terminal) to the high	
	electrically links the electrode	frequency power supply. See p. 5 of	
	terminal to the high frequency	translation and Figs. 8 and 9.	
	power supply." D.L. 353 at 2.		
		Dr. laylor's testimony at 1r, 1295.	

Anticipation by The Elsässer/Roos Article DTX-59A and 59B

· · · · · · · · · · · · · · · · · · ·	_
ArthroCare strongers and ArthroCare did not offer any rebuttal evidence or dispute that the Elsusser/Roos Article met this limitation at trial.	
ses a le) power nd Figs. utting	Dr. Taylor's testimony at Tr. 1298-99.
Claim 45 of the '536 Patent The Court's Claim Construction a return electrode electrode, the term 'return electrode lectrode, the term 'return electrode (return electrode) recurs and Roos Article discloses a groupled to the electrode, the term 'return electrode having a larger area of contact than an active electrode, thus affording a lower larger area of contact than the cutting a larger area of contact	
Claim 45 of the '536 Patent a return electrode electrically coupled to the electrosurgical power supply, and	

Anticipation by The Elsisser/Roos Article DTX-59A and 59B

Toin 45 of the 1576 Patent	The Court's Claim Construction	Smith & Nephew's Evidence	ArthroCare's Position
a electrically conducting	"Consistent with the prosecution	"[The device] offer[s] the high-frequency	ArthroCare did not offer any
In execution of directing	history, the phrase 'electrically	current a path to balance the potential	rebuttal evidence.
lectrically conducting fluid	conducting fluid supply' shall be	difference that would be so short and	<u>· </u>
the tarvet site such that the	construed to mean 'a medical	offer such a low resistance that aberrant	ArthroCare did cross-examine
lectrically conducting fluid	container that stores electrically	currents or leakage currents do not even	Dr. Taylor with respect to
enerates a current flow path	conducting fluid." An example of	_	whether the Elsasser and
etween the return electrode	a medical container is an IV bag.		Roos Article disclosed
and the electrode terminal.	An example of electrically	through the adjacent tissue to be cut and	efectrically conductive fluid.
	conducting fluid is isotonic saline."	the irrigation liquid." P. 4 of translation	However, ArthroCare did not
	DI 353 at 2	(emphasis added); see also p. 5 and Figs.	rebut Dr. Taylor's testimony
			on this point, nor did it
	"Consistent with the ordinary		overcome the explicit
	definition, electrically conducting	Dr. Taylor's testimony at Tr. 1299.	disclosure found in the
	fluid and electrically conductive		Elsasser and Roos Article
	fluid' shall be construed to mean		
	any fluid that facilitates the passage		
	of electrical current. Examples of		
	electrically conducting fluids are		
	blood and saline." Id. at 3.	•	
•	Directing or delivering the		
	electrically conductive fluid to the	•	
	target site "shall be construed		
	consistent with its ordinary		
	meaning; no further construction is		
	necessary. Ig. at 3.		J

Anticipation by The Elsässer/Roos Article DTX-59A and 59B

ArthroCare's Position	See above.		ArthroCare did not offer any	rebuttal evidence or dispute that the Elsässer/Roos Article	met this limitation at trial.						
Smith & Nenhew's Evidence	The Eleaster and Roos Article discloses	all the limitations of claim 45 as shown	In the device of Figs. 8 and 9 of the	Elsasser and Roos Article, the "metal	l ring that forms are noticed of the	endoscope, which is the shaft of the	probe - "the incorporation of the neutral	electrode as a metal ring into the chu of	the resectoscope snatt [times] proved	· · · · · · · · · · · · · · · · · · ·	Dr. Taylor's testimony at Tr. 1299-300.
	Clain 46 of the '536 Patent The Court's Claim Construction The Riefszer and Roos Article			The Court did not construe this limitation.		-			· · · · · · · · · · · · · · · · · · ·		-
	Claim 46 of the '536 Patent	An electrosurgical system as		the return electrode forms a	electrosurgical probe.						

ArthroCare's Position	See above.	re ArthroCare did not offer any rebuttal evidence or dispute that the Elsässer/Roos Article met this limitation at trial.	
S. it. P. Nanhaw's Evidence	The Blatsser and Roos Article discloses all the limitations of claim 45 as shown	The target sites described in the Elsässer rebuttal evidence or dispute and Roos Article are the prostate and Roos Article are the prostate and bladder, which are located in the abdominal cavity. P. 5 of translation. Dr. Taylor's testimony at Tr. 1300.	
	Claim 56 of the '336 Patent The Court's Claim Construction The electrosugical system of	the target site is selected from The Court did not construe this the group consisting limitation. essentially of the abdominal cavity, thoracic cavity, knee, shoulder, hip, hand, foot, elbow, mouth, spine, ear, nose, throat, epiderrnis and	
;	Claim 56 of the 436 Patent The electrosurgical system of	the target site is selected from the group consisting essentially of the abdominal cavity, thoracis cavity, thoracis cavity, thoracis cavity, hand, foot, shoulder, hip, hand, foot, elbow, mouth, spine, ear, nose, throat, epidermis and	Armis of the patient's body.

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BRIEF FILE

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IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

ARTHROCARE CORPORATION,)
Plaintiff,	
٧.) C.A. No. 01-504 (SLR)
SMITH & NEPHEW, INC.,	}
Defendant.	}

ARTHROCARE'S ANSWERING BRIEF IN OPPOSITION
TO SMITH & NEPHEW'S RULE 50(b) MOTION FOR
JUDGMENT AS A MATTER OF LAW

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July 30, 2003

patent had substantially the same current density. 11 (Tr. 1385). Thus, the Doss '007 patent does not disclose a return electrode because the Court's claim construction requires a return electrode to have a "lower current density" than the active electrode.

The Jury's Verdict That Neither The Roos And Elsasser Article Nor The Roos '198 Patent (the "Roos References") Anticipates The '536 Patent Should Not Be Disturbed.

The jury's determination that Smith & Nephew failed to meet its burden of proving invalidity is substantially supported by the fact that the Roos references were disclosed to the PTO during the reexamination of the '536 patent. (Tr.1336-38, PX 7). A board of three examiners reviewed the patentability of the asserted claims of the '536 patent in light of the Roos references during the reexamination and concluded that they did not render any of the claims unpatentable. (Tr. 1337-38). The PTO issued a Notice of Intent to Issue Reexamination Certificate on March 14, 2003. (Tr. 1538-40). Thus, the jury's determination that Smith & Nephew failed to meet its burden as to the Roos references must be viewed in light of the fact that Smith & Nephew's burden in proving anticipation was "more difficult" to meet.

As with the Doss '007 patent, Smith & Nephew failed to show that there is a connector near the proximal end of the shafts of the devices disclosed in the Roos references that connects the electrode terminal to the generator, as required by claims 46, 47 and 56 of the '536 patent. Dr. Taylor admitted that there is no disclosure of the location of a connector anywhere in the Roos '198 patent. (Tr. 1371-72). As for the Roos and Elsässer article, Dr. Taylor identified no disclosure in the article which described the function of the structure at the proximal end of the device which he contended was a connector. (Tr. 1298). The jury was free to disregard his testimony as insufficient to show a connector for "electrically coupling the electrode terminal to

Although Dr. Taylor tried to explain away his deposition testimony as a mistake, the jury was free to reject his trial testimony. (Tr. 1385-86).

the electrosurgical power supply," especially since Dr. Taylor had used the word "connector" to describe a structure that connected the device in the Pao '499 patent to a fluid supply. (Tr. 1311). In light of this lack of evidence of a connector, Smith & Nephew cites to several passages in the Roos references in a misguided attempt to show that a connector is inherent. The first passage Smith & Nephew quotes (D.I. 459 at 30) is from the '198 patent and discusses a cable leading to the return electrode, not a connector for electrically coupling the active electrode, as required by the asserted claims. The second passage Smith & Nephew cites, also from the '198 patent, discusses only an "insulated cable means," which is a conductor, not a connector, and in any event does not disclose its location with respect to the proximal end. (Id.) Finally, Smith & Nephew points to figure 9 in the Roos and Elsässer article as evidence of a connector. (D.I. 459 at 30). Figure 9, however, does not disclose what the structure at the proximal end actually does, such as whether it connects the active electrode, the return electrode, or a fluid supply, or has some other function altogether.

Dr. Taylor's testimony also did not establish that a connector near the proximal end of the shaft for coupling the electrode terminal to the generator is inherently disclosed in either of the Roos references. As Smith & Nephew points out, Dr. Taylor testified that "you do realize that all resectoscopes have connectors at the back of the resectoscope." (Tr. 1371). This testimony, however, was properly rejected by the jury because it lacked any basis, was conclusory, was not corroborated with any documents, and does not specify what the "connector" couples together. Similarly, Dr. Taylor's testimony that "there are no resectoscopes on the market that don't have a connector at the end, on the back of the resectoscope" (Tr. 1372) is insufficient because the mere fact that devices on the market today may have connectors does not establish (a) that the connector is one that connects the electrode terminal to the generator, or (b) that a connector is inherent in the Roos references that were published over 20 years ago. Rosco, Inc. v. Mirror Lite Co., 304 F.3d 1373, 1380 (Fed. Cir. 2002) ("inherent anticipation requires that the missing

descriptive material is 'necessarily present,' not merely probably or possibly present, in the prior art").

.

Dr. Taylor's admissions also clearly establish that the Roos references do not disclose the use of an electrically conducting fluid. Dr. Taylor testified that the Roos references do not disclose the use of either saline or Ringer's lactate. (Tr. 1340-43, 1375). He also testified that the Roos references describe the use of prior art monopolar devices for TURP procedures, in addition to the bipolar devices Smith & Nephew alleges anticipate. (Tr. 1340-42, 1374-75). As Dr. Taylor testified, the liquid used in these prior art monopolar devices for TURP procedures was electrically non-conducting. (Id.). This is significant because Dr. Taylor conceded that the Roos references do not differentiate between the liquid used with the bipolar devices and the liquid used with the monopolar devices. (Tr. 1343-44 ("washing water" and "washing liquid"), 1376-77 ("irrigation liquid"), 1350-51). From this, the jury was free to conclude that the liquid described in the Roos references was not electrically conducting fluid.

In addition, Dr. Taylor's testimony as to Figure 5 of the Roos '198 patent establishes that the fluid it mentioned was not electrically conducting. Dr. Taylor agreed that if the liquid disclosed in Figure 5 of the Roos '198 patent were electrically conducting, there would be no need for the steel band described in Figure 5 to rest "on the tissue in large area form so that good electrical contact is ensured," as described in the '198 patent (Tr. 1345). Because Dr. Taylor testified that the same fluid is used for all of the embodiments of the '198 patent, there can be no doubt that the fluid disclosed in the '198 patent was not electrically conducting. (Tr. 1343-44, 1350-51, 1376-77).

Dr. Taylor's testimony concerning a later issued patent to Roos, the '667 patent, also shows that the fluid mentioned in the '198 patent was not electrically conducting. Specifically, Dr. Taylor agreed that if the fluid used in '198 patent had been an electrically conducting fluid, then the subsequent '667 patent would not have stated, as it did, that the device in the '198 patent did not work. (Tr. 1364-66). Moreover, Dr. Taylor conceded that if the device disclosed in the

'198 patent had used electrically conducting fluid, then the '667 patent would not have described the return electrode of the '198 patent as only being able to "enter into electrical contact with the cutting electrode electrolytically via the secretion which is present during the cutting process." (Tr. 1366). In light of Dr. Taylor's admissions, the jury was free to conclude that Smith & Nephew did not meet its burden of proving that the Roos '198 patent anticipated the asserted claims of the '536 patent.

Smith & Nephew makes much of the fact that claim 1 of the '198 patent refers to "liquid to provide electrical conductance." (D.I. 459 at 32). This statement, however, begs the question rather than answering it. Dr. Taylor readily conceded that even non-conducting fluids will conduct electrical current. (Tr. 1373-75). This testimony is consistent with Figure 3 of the Roos and Elsässer article, which clearly shows current flux lines passing from the treatment electrode to the endoscope shaft through electrically non-conducting fluid. (Id., DTX 594A). From this, the jury was free to conclude that simply because a fluid will conduct some amount of current does not make it an electrically conducting fluid, and thus that Smith & Nephew failed to show anticipation by clear and convincing evidence with the Roos references.

Smith & Nephew also cites to the Roos and Elsässer article, which states that "[the device] offer[s] the high-frequency current a path to balance the potential difference that would be so short and offer such a low resistance that aberrant currents or leakage do not even occur." (D.I. 459 at 32). Smith & Nephew did not argue at trial that this portion of the Roos article discloses an electrically conducting fluid, nor could it have, because this portion of the article is not referring to the conductive qualities of the fluid. Instead, it is referring to the relatively lower resistance between the electrodes in the bipolar, as opposed to monopolar, configurations that results from the shorter distance between electrodes in a bipolar device (both electrodes are positioned close together in the vicinity of the surgical site) than in a monopolar device (the return electrode is positioned away from the surgical site outside the patient's body).

CLERK U.S. DISTRICT COURT DISTRICT CF DELAWARE

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE 12 PM 4: 37

- ARTHROCARE CORPORATION,

Plaintiff,

٧.

SMITH & NEPHEW, INC.

C.A. No. 01-504-SLR

Defendant.

SMITH & NEPHEW, INC.,

Counterclaim Plaintiff,

Y

ARTHROCARE CORPORATION, AND ETHICON, INC.,

Counterclaim Defendants.

SMITH & NEPHEW, INC.'S MOTION TO STAY INJUNCTION

Defendant Smith & Nephew, Inc. ("Smith & Nephew") hereby moves this Court for an order staying the injunction granted by the Court's March 10, 2004 Order pending the outcome of appeal for the reasons more fully set forth in the memorandum accompanying this motion

Dated: March 12, 2004

FISH & RICHARDSON P.C.

By: 👱

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IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

ARTHROCARE CORPORATION,	
Plaintiff,	
v.	
SMITH & NEPHEW, INC.	C.A. No. 01-504-SLR
Defendant.	
SMITH & NEPHEW, INC.,	
Counterclaim Plaintiff, v.	
ARTHROCARE CORPORATION, AND ETHICON, INC.,	
Counterclaim Defendants.	
PROPOS	ED ORDER
The Court having considered the me	otion to stay injunction, filed by Smith &
Nephew, and all supporting memoranda an	d exhibits, and ArthroCare's response thereto,
and good cause having been shown therefo	re:
IT IS HEREBY ORDERED this	day of 2004 that the
injunction granted by the Court's March 10), 2004 Order (D.I. 483) be stayed pending the
outcome of the appeal.	•
·	UNITED STATES DISTRICT JUDGE

CERTIFICATE OF SERVICE

I hereby certify that on this 12th day of March, 2004, a true and correct copy of

SMITH & NEPHEW, INC.'S MOTION TO STAY INJUNCTION was caused to be

served on the attorneys of record at the following addresses as indicated:

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Attorney for Plaintiff/Counterclaim Defendant Ethicon, Inc.

William J. Marsden

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RULE 7.1.1 CERTIFICATE

I hereby certify that I have made a reasonable effort to contact counsel for ArthroCare on the matters set forth in the Motion. I further certify that I have been unable to reach ArthroCare's counsel and reasonably assume that ArthroCare opposes the Motion.

Dated: March 12, 2003

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

ARTHROCARE CORPORATION,

Plaintiff,

SMITH & NEPHEW, INC.

C.A. No. 01-504-SLR

Defendant.

SMITH & NEPHEW, INC.,

Counterclaim Plaintiff,

CONFIDENTIAL FILED UNDER SEAL

ARTHROCARE CORPORATION, AND ETHICON, INC.,

Counterclaim Defendants.

SMITH & NEPHEW'S OPENING BRIEF IN SUPPORT OF ITS MOTION TO STAY INJUNCTION

Dated: March 12, 2004

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Attorneys for Defendant SMITH & NEPHEW, INC.

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A 18189 - 18193



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FISH & RICHARDSON, RC. BOSTON OFFICE

REEXAMINATION COMMUNICATION TRANSMITTAL FORM

PATENT NO. 5,617, 536

ART UNIT 3763

Enclosed is a copy of the latest communication from the Patent and Trademark Office in the above identified reexamination proceeding. 37 C.F.R. 1.550(e).

Where this copy is supplied after the reply by requester, 37 C.F.R. 1.535, or the time for filing a reply has passed, no submissions on behalf of the reexamination requester will be acknowledged or considered. 37 C.F.R. 1.550(e).

Docketed By Practice Water Spt.
Action : Water Character Spt.
The Tribo: ORD III.
Durdline: St. V.
Initials:
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Due Date: And Date: Miling

PTCL-448 (2.4C)



United states department of commerce Patent and Trademark Office

Addres: ASSISTANT COMMISSIONER FOR PATENTS Westington, D.C. 20231

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APPLICATION HOJ	FILING DATE	FIRST NAMED INVENTOR!	ATTORNEY DOCKET NO.
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90/006,597	APRIL 9, 2003	5.697.536	

JOHN T. RAFFLE ARTHROCARE CORPORATION 680 VAQUEROS AVENUE SUNHYVALE, CA 94085

DANNER HAYES, M. ART UNIT PAPER 3763

DATE MAILED: JUNE 30, 2003

Please find below and/or attached an Office communication concerning this application or proceeding.

oc: William E. Booth, 3rd party attorney

PTO-90C (Rev.3-96)

	Control Na.	- Patent Under R	eexamination
<i>:</i>	90/006.697	5697536	
Order Granting / Denying Request For	Examiner	Art Unik	
Ex Parte Reexamination	Michael J Hayes	3763	
-The MAILING DATE of this communication app			}
The request for experie reexamination filed on been made. An identification of the claims, the detainmention are attached.	9 April 2003 has been on references relied upon,	nsidered and a deter and the rationale sup	mination has poorling the
Attachments: a) PTO-892, b) P		her:	
1. The request for ex parte reexamination is			
RESPONSE TIMES ARE SET AS	•		
For Patent Owner's Statement (Optional): TO (37 CFR 1.530 (b)), EXTENSIONS OF TIME	WE CONSTRUCT DI		. 1
For Requester's Repty (optional); TWO MOI Patent Owner's Statement (37 CFR 1.535). If Patent Owner does not file a timely statent is permitted.	nent under 37 CFR 1.530	ervice of any timely i IS TIME PERIOD IS I(b), then no reply by	Med PERMITTED. requester
2. The request for ex parte reexamination	is DENIED.		
This decision is not appealable (35 U.S.C. 3 Commissioner under 37 CFR 1.181 within CCFR 1.515(c)). EXTENSION OF TIME TO I AVAILABLE ONLY BY PETITION TO SUS 37 CFR 1.183.	FILE SUCH A PETITION PEND OR WAIVE THE	UNDER 37 CFR 1.1 REGULATIONS UN	81 ARE
in due course, a refund under 37 CFR 1.26	per of ebern ed like (o) (uester:	
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b) by credit to Deposit Account No	or		
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		Michael J Hayes Primary Exeminer Art Unit: 3763	
co:Requester (If third party requester)		Park of Paper	

Page 2

Application/Control Number: 90/006,597

Art Unit: 3763

Recamination

A substantial new question of patentability affecting claims 1, 2, 5, 9, 14, 15, 26, 28, 30-33, 36, 38, 40, 42-47, 49, 53, 56, 58, 59, 61, and 63 of United States Patent Number 5,697,536 is raised by the request for reexamination.

Extensions of time under 37 CFR 1.136(a) will not be permitted in these proceedings because the provisions of 37 CFR 1.136 apply only to "an applicant" and not to parties in a reexamination proceeding. Additionally, 35 U.S.C. 305 requires that reexamination proceedings "will be conducted with special dispatch" (37 CFR 1.550(a)). Extension of time in reexamination proceedings are provided for in 37 CFR 1.550(c).

The request indicates that Requestor considers claims 1, 2, 5, 9, 14, 15, 26, 28, 30-33, 36, 38, 40, 42-47, 49, 53, 56, 58, 59, 61, and 63 are unpatentable over ROOS (U. S. Patent No. 4,116,198), Uber ein Instrument zur leckstromfreien transurethralen Resektioin (Elsasser and Roos article), PAO (U. S. Patent No. 4,805,616), PAO (U. S. Patent No. 4,674,499), DOSS (U. S. Patent No. 4,381,007), KAMERLING (U. S. Patent No. 5,217,459), or RYDELL (U. S. Patent No. 5,007,908).

The above new question of patentability is based solely on patents and/or printed publications already cited/considered in an earlier concluded examination of the patent being examined. On November 2, 2002, Public Law 107-273 was exacted. Title III, Subtitle A, Section 13105, part (a) of the Act revised the reexamination statute by adding the following new last sentence to 34 U.S.C. 303(a) and 312(a):

"The existence of a substantial new question of patentability is not precluded by the fact that a patent or printed publication was previously cited by or to the Office or considered by the Office."

Application/Control Number: 90/006,597
Art Unit: 3763

For any reexamination ordered on or after November 2, 2002, the effective date of the statutory revision, reliance on previously cited/considered art, i.e., "old art," does not necessarily preclude the existence of a substantial new question of patentability (SNQ) that is based exclusively on that old art. Rather, determinations on whether a SNQ exists in such an instance ahall be based upon a fact-specific inquiry done on a case-by-case basis.

In the present instance, there exists a SNQ based solely on ROOS (U. S. Patent No. 4,116,198), Uber ein Instrument zur leckstromfreien transurethralen Resektioin (Elsasser and Roos article), PAO (U. S. Patent No. 4,805,616), PAO (U. S. Patent No. 4,674,499), DOSS (U. S. Patent No. 4,381,007), KAMERLING (U. S. Patent No. 5,217,459), or RYDELL (U. S. Patent No. 5,007,908).

The old art listed above has been presented in a new light with a material new argument or interpretation.

Requestor's argument concerning the interpretation of the limitation of claim 1 of Roos ('198) (Exhibit A) of liquid providing electrical conductance between electrodes presents the old art in a new light. The declaration of Eberhard Roos (Exhibit 1) also presents old art Roos ('198) and the Elsasser and Roos article in a new light.

Old art Pao ('616), Pao ('499), Kamerling ('459), Doss ('007), and Rydell ('908) were cited in the prosecution of patent '536 or in reexamination 90/005601 (the recommination of the '536 patent). Requestor's arguments, as presented in request for reexamination, received 5/07/03 presents this old art in a new light, with material new argument or interpretation as compared with its use in the earlier examinations.

Page 4

Application/Control Number: 90/006,597 Art Unit: 3763

Requestor's new arguments concerning the sterile salt solution disclosed by Pao ('616) and its inherent properties presents the art in a new light.

Requestor presents materially new arguments with respect to Pao '499 disclosure of introducing saline to the electrosurgical site and the saline's inherent property of conduction.

Requestor's new arguments concerning the saline presence at the electrodes site and its ability to help generate a current flow path with respect to Kamerling ('459) presents a materially new argument.

Pao '499, Doss ('007), and Rydell ('908) were cited in examination of patent '536, but their relevance to patentability of the claims was not discussed so reexamination based on these prior art is proper. See MPEP § 2242 (A)(2).

The patent owner is reminded of the continuing responsibility under 37 CFR 1.565(a), to apprise the Office of any litigation activity, or other prior or concurrent proceeding, involving Patent No. 5,697,536 throughout the course of this reexamination proceeding. See MPEP §5 2207, 2282 and 2286.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (703) 305-5873. The examiner can usually be reached Monday-Thursday, 7:00-4:30, and on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler, can be contacted at (703) 308-3552. The fax number for submitting official papers is (703) 872-9302. The fax number for submitting after final papers is (703) 872-9303.

mjh 27 June 2003

MICHAEL J. HAYES PRIMARY EXAMINER

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These pages have been removed from the non-confidential appendix due to confidential designations

CERTIFICATE OF SERVICE

I hereby certify that on this 12th day of March, 2004, a true and correct copy of the SMITH & NEPHEW'S MOTION FOR RECONSIDERATION OF ORDERS GRANTING ARTHROCARE'S MOTION TO DISMISS SMITH & NEPHEW'S ANTITRUST COUNTERCLAIM AND GRANTING ARTHROCARE'S MOTION FOR PERMANENT INJUNCTION was caused to be served on the attorneys of record at the following addresses as indicated:

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Attorney for Plaintiff/Counterclaim Defendant Ethicon, Inc.

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IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

ARTHROCARE CORPORATION.

Plaintiff.

SMITH & NEPHEW, INC.

C.A. No. 01-504-SLR

CLERK U.S. DISTRICT COL DISTRICT OF CELAWAR

Defendant,

SMITH & NEPHEW, INC.,

Counterclaim Plaintiff,

ARTHROCARE CORPORATION, AND ETHICON, INC.,

Counterclaim Defendants.

SMITH & NEPHEW'S UNOPPOSED MOTION TO LIFT STAY TO PERMIT SMITH & NEPHEW TO FILE AN ANSWERING BRIEF IN OPPOSITION TO ARHTROCARE'S MOTION TO DISMISS SMITH & NEPHEW'S ANTITRUST COUNTERCLAIM

Defendant, Smith & Nephew, Inc. ("Smith & Nephew") hereby moves to lift the stay previously imposed by the Court and permit Smith & Nephew to file an Answering Brief in opposition to the motion filed by ArthroCare Corp. ("ArthroCare") to dismiss Smith & Nephew's antitrust counterclaim. ArthroCare states that it does not oppose this motion. In support of this motion, Smith & Nephew states as follows:

1. On May 27, 2003, ArthroCare filed a Motion to Dismiss Smith & Nephew's Antitrust Counterclaim. (D.I. 429, "Motion to Dismiss"). Thereafter, on June 9, 2003, before Smith & Nephew's answering brief was due, the Court held a telephone conference to set a briefing schedule for all post-trial motions in this case. (D.I. 447).

- 2. During that June 9, 2003 teleconference, with respect to all matters relating to the issues of antitrust, damages and willfulness, the Court stayed all further proceedings, including briefing with respect to the Motion to Dismiss. (*Id.* at 10:15-22, 14:21-23, 15:2-5, 15:21-16:1). The Court also advised the parties that no formal order would issue because the orders staying the various issues discussed during the teleconference would be reflected in the transcript, (*Id.* at 12:21-24).
- 3. No further order has ever issued which lifted or otherwise addressed the Court's stay of any further briefing with respect to ArthroCare's Motion to Dismiss.
- 4. On March 10, 2004 the Court issued Orders (D.I. 482 and 484) in which the Court granted ArthroCare's Motion to Dismiss, as well as its motion for a permanent injunction. ("Motion for Permanent Injunction") (D.I. 424).
- 5. In the memorandum opinion supporting the Court's Order granting the Motion to Dismiss, the Court inferred from the absence of an answering brief filed by Smith & Nephew that the motion was not opposed: "Smith & Nephew has not responded... [t]he court, therefore, presumes that Smith & Nephew does not oppose the

Defendant Smith & Nephew has filed a motion pursuant to Local Rule 7.1.5 for reconsideration (D.I. 488) because the Order granting the Motion to Dismiss was based on two mistaken assumptions: 1) that the motion was unopposed; and 2) that the viability of Smith & Nephew's antitrust counterclaim depends on a showing that this action was objectively baseless "sharm" litigation. Because the erroneous dismissal of Smith & Nephew's antitrust counterclaims was the predicate for the court's finding that "it is not premature to enter an injunction" (D.I. 483 at 90, n.29), Smith & Nephew also requested reconsideration of the court's Order granting the Motion for Permanent Injunction. The injustice of the ruling on the antitrust counterclaim was compounded when ArthroCare ignored the Court's stay of briefing in opposing the motion for reconsideration and instead repeated its arguments in support of its motion to dismiss, knowing that Smith & Nephew again would have no opportunity to respond. Local Rule 7.1.5 ("The Court will determine from the motion and answer whether reargument will be granted."); Stairmaster Sports/Medical Products, Inc. v. Groupe Procycle, Inc., 25 F.Supp.2d 270, 292 (D. Del. 1998) (Local Rule 7.1.5 "permits filing of only one brief per side with an emphasis on brevity ... StairMaster, apparently anxious to get the last word, filed a reply brief while Local Rule 7.1.5 distinctly sets out that the Court will determine from the motion and answer whether argument will be granted.").

motion." (D.I. 483, at n. I). This presumption was in error. Smith & Nephew made its opposition to the Motion to Dismiss known when it opposed the Motion for Permanent Injunction, as the Court acknowledged. (Id.). It was given no further opportunity to oppose because the Court stayed briefing on the Motion to Dismiss and all other activity related to the antitrust counterclaim.

- 6. Moreover, because the Court did not have a brief in opposition to the Motion to Dismiss, it adopted ArthroCare's misleading, incomplete and erroneous characterization of the counterclaim as a simple "sham" litigation claim and found it barred by the jury's verdict and the Noerr-Pennington doctrine. In particular, the Court characterized Smith & Nephew's antitrust counterclaim as "premised on the idea that ArthroCare and Ethicon? filed 'sham' litigation against Smith & Nephew to prevent or restrain it from entering the arthroscopic surgery market." Undoubtedly, this incomplete and inaccurate characterization of the antitrust counterclaim was derived in large part from the unanswered arguments made in ArthroCare's brief in support of its Motion to Dismiss. (D.I. 430). For example, ArthroCare argued there that, "Smith & Nephew had to make these allegations [that the lawsuit was objectively baseless] because ArthroCare's patent infringement suit cannot give rise to antitrust liability unless Smith & Nephew pleads and proves that ArthroCare has engaged in 'sham litigation.'" (D.I. 430 at 6). (emphasis added). However, Smith & Nephew's antitrust counterclaim is not so limited.
- 7. Fundamental fairness, as well as due process, requires that Smith & Nephew be given an opportunity to be heard on the merits in connection with the Motion to Dismiss. Dougherty v. Harper's Magazine Co., 537 F.2d 758 (3d Cir. 1976). In Dougherty, the court stated:

Rule 12(d), FRCP requires that a Rule 12(b)(6) motion for dismissal ... may be disposed of only after a hearing, which affords an opportunity to present legal arguments either orally, in writing, or both at the District Court's discretion. The right to hearing is "the essence of our judicial

² Ethicon, Inc. is not a plaintiff in this case. Ethicon was added as a counterclaim defendant on the antitrust counterclaim included in the Amended Answer and Counterclaims of Smith & Nephew, Inc. (D.I. 219).

system, and the judge's feeling that the case is probably frivolous does not justify bypassing that right." ... In Jordan v. County of Montgomery, Pennsylvania, ... we held that an order dismissing a complaint under Rule 12(b)(6), entered without affording the plaintiff an opportunity to be heard, must be reversed. We note that in Council of Federated Organizations v. Mize, 339 F.2d 898 (5th Cir. 1964), the Court characterized as a denial of due process the entry of an order dismissing the complaint for failure to state a claim without giving the plaintiff an opportunity to be heard.

Id. at 761 (internal citations omitted). Similarly, the Supreme Court has held:

Under Rule 12(b)(6), a plaintiff with an arguable claim is ordinarily accorded notice of a pending motion to dismiss for failure to state a claim and an opportunity to amend the complaint before the motion is ruled upon. These procedures alert him to the legal theory underlying the defendant's challenge, and enable him meaningfully to respond by opposing the motion to dismiss on legal grounds or by clarifying his factual allegations so as to conform with the requirements of a valid legal cause of action. This adversarial process also crystallizes the pertinent issues and facilitates appellate review of a trial court dismissal by creating a more complete record of the case.

Neitzke v. Williams, 490 U.S. 319, 329-30 (1989).

Conclusion

8. For the reasons set forth herein, Smith & Nephew respectfully requests that the Court lift its June 9, 2003 stay with respect to briefing on ArthroCare's Motion to Dismiss, and allow Smith & Nephew to file an Opposition to the Motion.

Dated: April 6, 2004

FISH & RICHARDSON P.C.

Bv

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Attorneys for Defendant SMITH & NEPHEW, INC.

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RULE 7.1.1 CERTIFICATE

I hereby certify that I have contacted counsel for ArthroCare on the matters set forth in the Motion. I further certify that I ArthroCare's counsel does not oppose our motion to lift the stay to permit Smith & Nephew to file an answering brief.

Eugene B. Joswick

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

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CERTIFICATE OF SERVICE

I hereby certify that on this 6th day of April, 2004, a true and correct copy of the SMITH & NEPHEW'S UNOPPOSED MOTION TO LIFT STAY TO PERMIT SMITH & NEPHEW TO FILE AN ANSWERING BRIEF IN OPPOSITION TO ARHTROCARE'S MOTION TO DISMISS SMITH & NEPHEW'S ANTITRUST COUNTERCLAIM was caused to be served on the attorneys of record at the following addresses as indicated:

BY HAND DELIVERY
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Eugene B. Joswick

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[75]	Inventors:	Philip E. Eggers, Dublin, Ohio; Hire V. Thepliyal, Los Altos, Calif.	_	(List continued on next page.) FOREIGN PATENT DOCUMENTS			•	
[73]	Assignce:	Arthrocare Corporation, Sunnyvalc, Calif.	515 9 740 0 754 740 9007	437	12/1992 11/1996 1/1997	European Pat.	Off A61E	17/39
[21]	Appl No.:	61,958	WO 92/21	278	12/1992	WIPO	A611	17/39 R SAN
[22]	Filed: 1	ion. 22, 1995	WO 94/14 WO 97/00	383	7/1993 7/1994 - 1/1997	WIPO	A61B	17/36
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ध्य	Continuation-in-part of Ser. No. 445,219, Jun. 7, 1995, which is a continuation-in-part of Ser. No. 59,681, May 10, 1993, abandoned, which is a continuation-in-part of Ser. No. 958,977, Oct. 9, 1992, Pat. No. 5,366,443, which is a continuation-in-part of Ser. No. 817,575, Jun. 7, 1992, abandoned.		P.C. Nard Energy an Raad et a	La	(1989) 5 pedance 985) 1. 1	PUBLICATE PIE 1068:42- Peodback, Arthur Sure	ONS 49 Radio Proq	ucacy
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604/49, 113, 41; 606/27-32, 35, 38, 41

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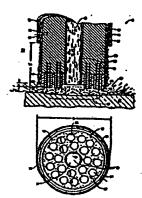
ABSTRACT

Primary Examiner—Manuel Mendez
Attorney, Agent, or Firm—Townsend and Townsend and
Crew LLP

ABSTRACT

An electrosurgical probe (10) comprises a shaft (E3) having an electrode array (58) at its distal end and a connector (19) at its proximal end for coupling the electrode array to a high frequency power supply (28). The shaft includes a return electrode (56) recessed from its distal end and enclosed within an insularing jacket (18). The return electrode defines as inacr passage (63) electrically connected to both the return electrode and the electrode array for passage of an electrically conducting liquid (50). By applying high frequency voltage to the electrode array and the return electrode, the electrically conducting liquid generates a current flow path between the return electrode array so that target tissue may be cut or ablated. The probe is particularly useful in dry environments, such as the mouth or abdominal cavity, because the electrically conducting liquid provides the accessary return current path conducting liquid provides the accessary return current path between the active and return electrodes.

56 Claims, 17 Drawing Sheets



Joint Trial Exhibit JTX 2

5,697,882 Page 2

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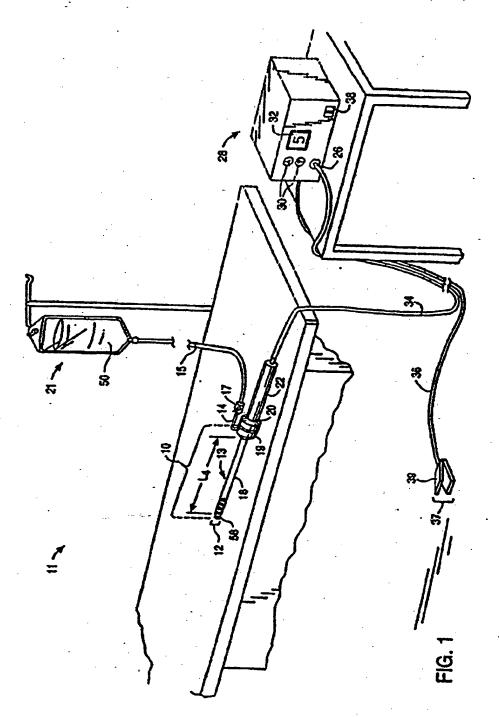
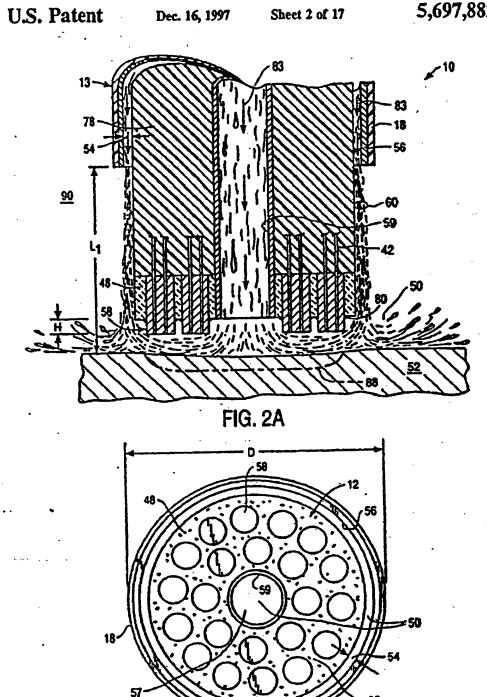
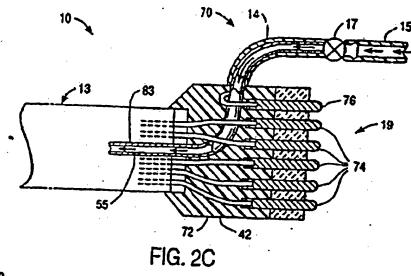


FIG. 2B





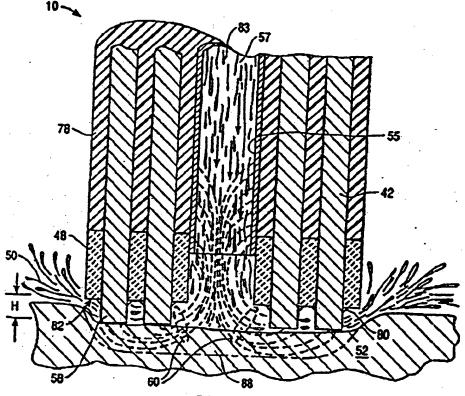


FIG. 3

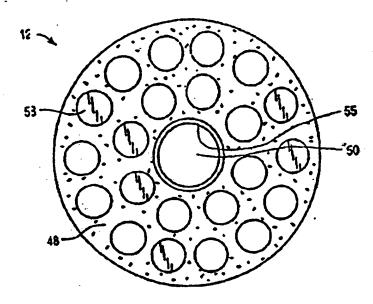


FIG. 4

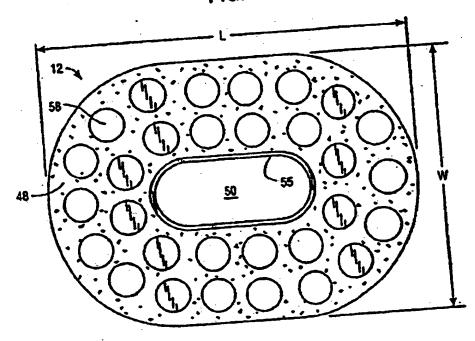


FIG. 5

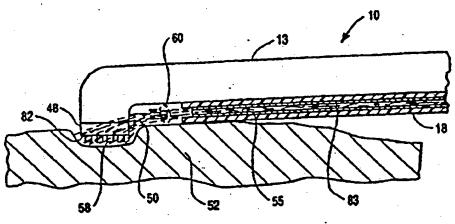


FIG. 6

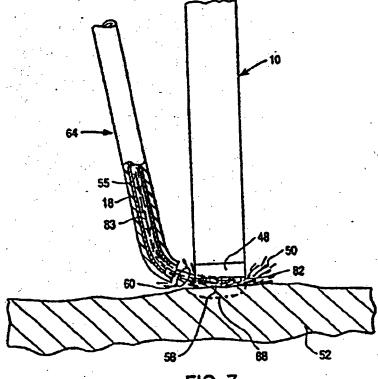


FIG. 7

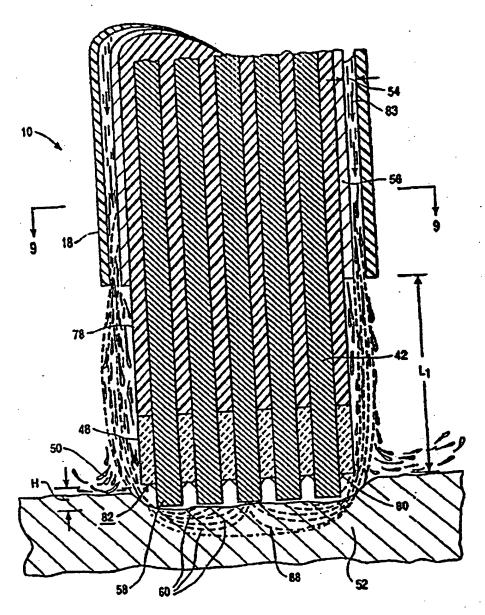


FIG. 8

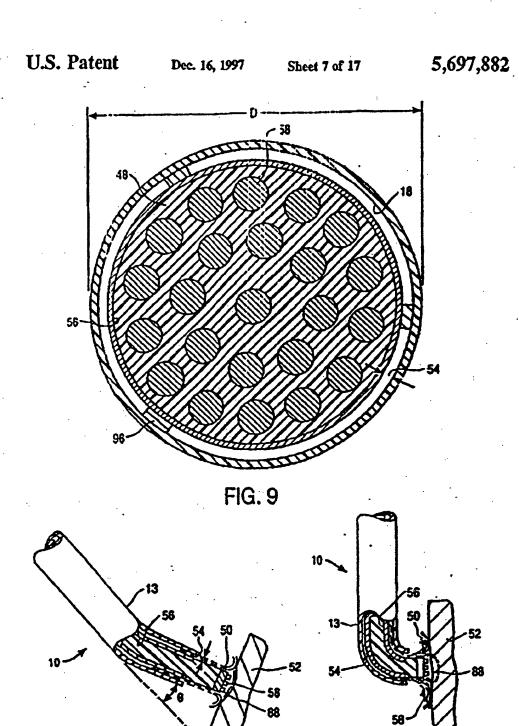
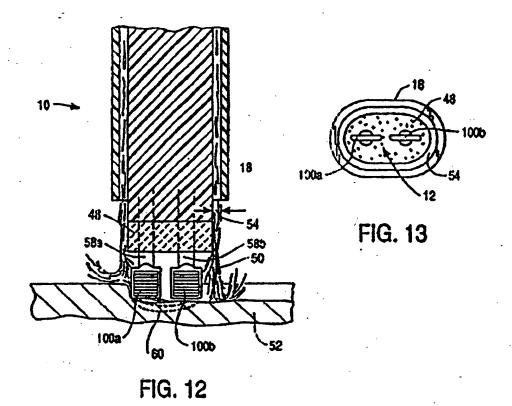
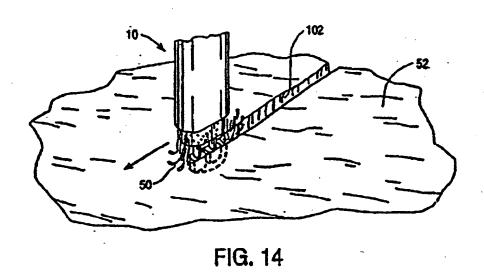


FIG. 11

FIG. 10





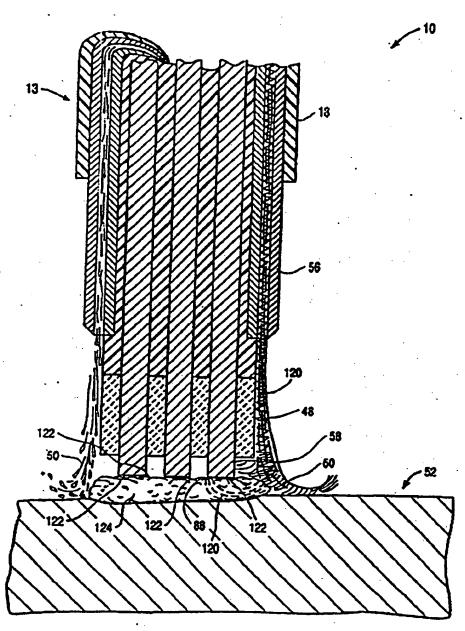
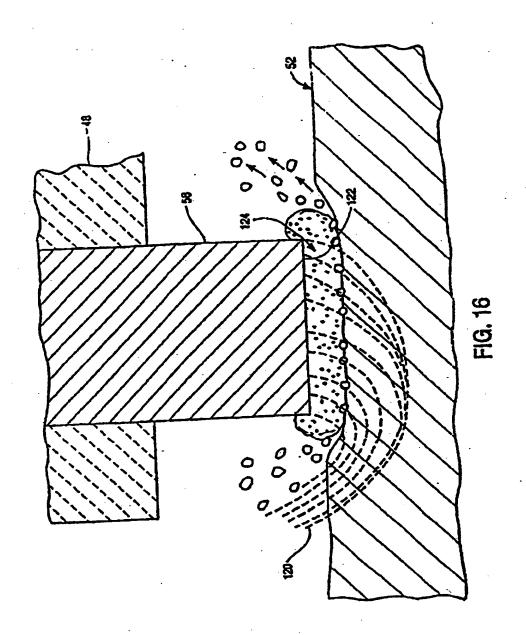
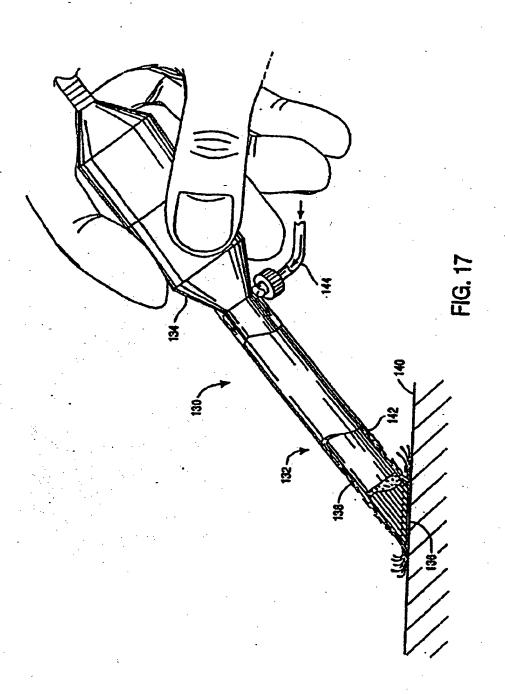


FIG. 15





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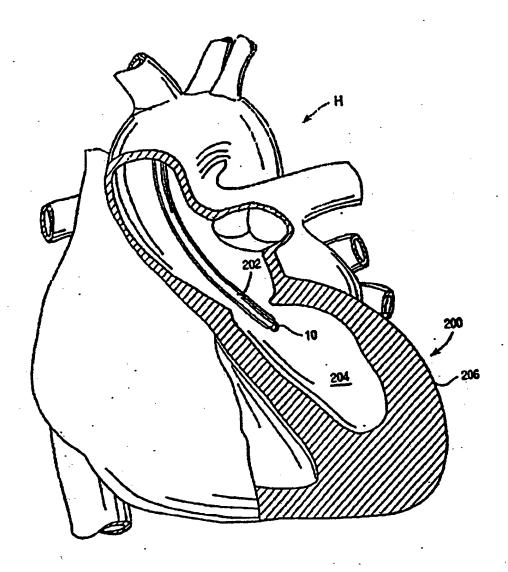


FIG. 18

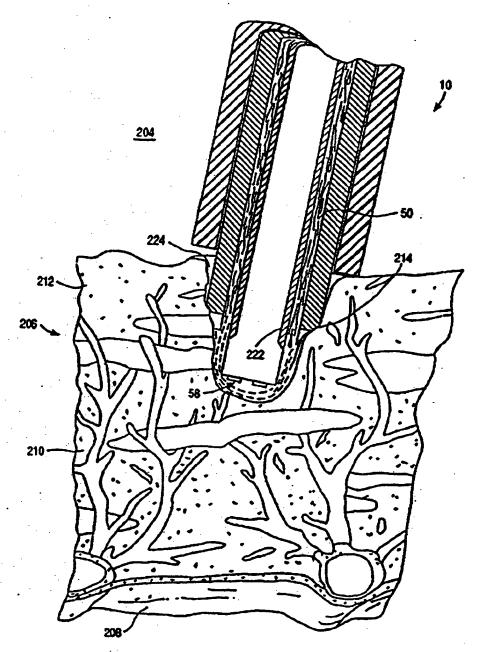


FIG. 19

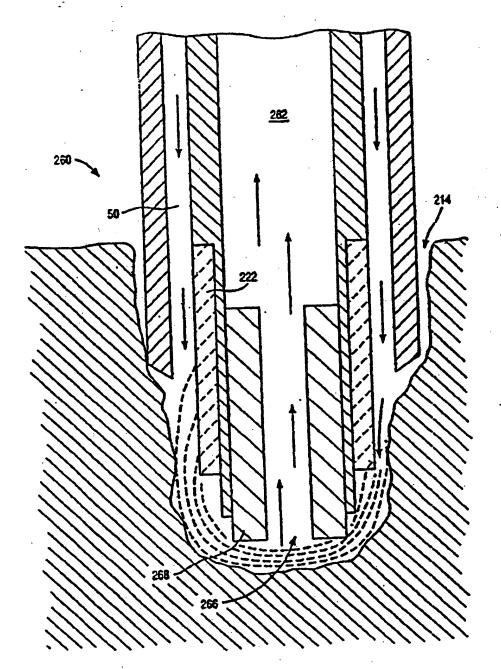
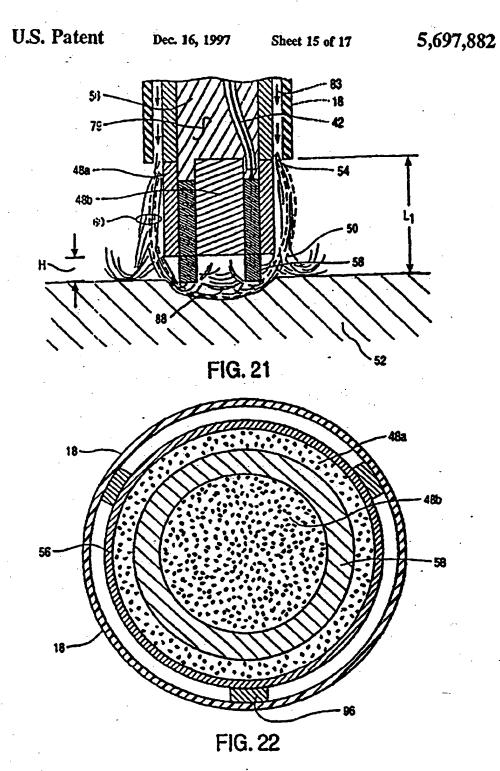


FIG. 20



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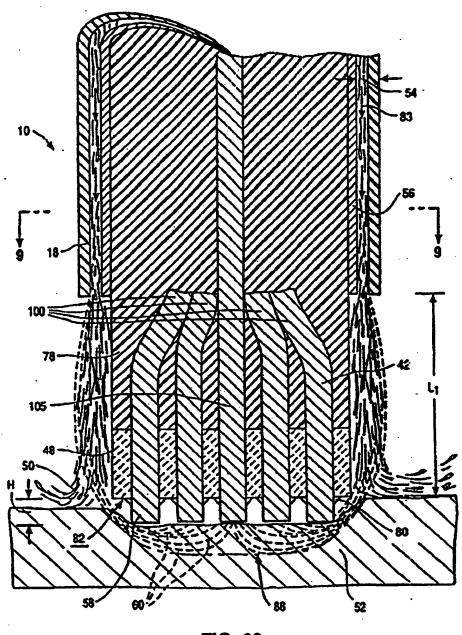


FIG. 23

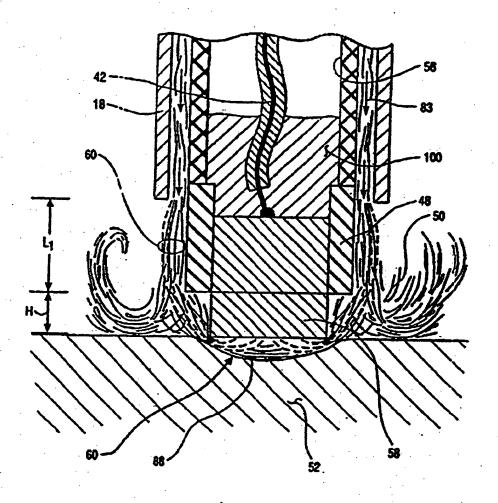


FIG. 24

SYSTEM AND METHOD FOR ELECTROSURGICAL CUTTING AND ABLATION

BACKGROUND OF THE INVENTION

The present invention is a continuation-in-part of application Ser. No. 08/485.219, filed on Jun. 7, 1995 and still presding, which was a continuation-in-part of PCT International Application, U.S. National Phase Serial No. PCII/ US94/05168, filed on May 10, 1994, which was a continuation-in-part of application Ser. No. 08/059.681, filed on May 10, 1993 and now abandoned, which was a continuation-in-part of application Ser. No. 07/958,977, filed on Oct. 9, 1992 now U.S. Pat. No. 5.366.443, which was a continuation-in-part of application Ser. No. 07/817, 575, filed on Jan. 7, 1992 now abandoned, the full disclosures of which are incorporated herein by reference.

PIPLD OF THE INVENTION

The present invention relates generally to the field of ²⁰ electrosurgery and, more particularly, to surgical devices and methods which employ high frequency voltage to cut and ablate tissue.

The field of electrosurgery includes a number of loosely related surgical techniques which have in common the application of electrical energy to modify the structure or integrity of patient tissue. Electrosurgical procedures usually operate through the application of very high frequency currents to cut or ablate tissue structures, where the operation can be monopolar or bipolar. Monopolar techniques rely on external grounding of the patient, where the surgical device defines only a single electrode pole. Bipolar devices comprise both electrodes for the application of current between their surfaces.

Electrorupical procedures and techniques are particularly advantageous since they generally reduce patient bleeding and trauma associated with cutting operations. Current elec-trosurgical device and procedures, however, suffer from a number of dissavantages. For example, monopolar devices generally direct electric current along a defined path from the exposed or active electrode through the patient's body to the return electrode, which is externally attached to a suitable location on the patient. This creates the potential danger that the electric current will flow through undefined paths in 45 the patient's body, thereby increasing the risk of unwanted electrical stimulation to portions of the patient's body. In addition, since the defined path through the patient's body has a relatively high impedance (because of the large distance or resistivity of the patient's body), large voltage differences must typically be applied between the return and active electrodes in order to generate a current suitable for ablation or cutting of the target tissue. This current, however, may inadvertently flow along body paths having less impod-ance than the defined electrical path, which will substan-tially increase the current flowing through these paths, possibly causing damage to or destroying tissue along and purcunding this pathway.

Bipolar electrosurgical devices have an inherent advantage over monopolar devices because the return current path does not flow through the patient. In bipolar electrosurgical devices, both the active and return electrode are typically exposed so that they may both contact tissue, thereby providing a return current path from the active to the return electrode through the tissue. One drawback with this 65 configuration, however, is that the return electrode may cause tissue desiccation of destruction at its contact point

with the patient's tissue. In addition, the active and return electrodes are typically positioned close together to ensure that the remm current flows directly from the active to the remm electrode. The close proximity of these electrodes generates the danger that the current will then across the electrodes, possibly impaking the electrical control system and/or damaging or destroying surrounding tissue.

The use of electrosurgical procedures (both mosopolar and bipolar) in electrically conductive environments can be further problematic. For example, many arthroscopic procedures require flushing of the region to be treated with isotonic saline (also referred to as normal saline), both to maintain an isotonic environment and to keep the field of viewing clear. The presence of saline, which is a highly conductive electrolytin, can also cause shorting of the electrosurgical electrode in both mosopolar and bipolar modes. Such shorting causes unnecessary heating in the treatment environment and can further cause non-specific tissue destruction.

Many surgical procedures, such as oral, isparoscopic and open surgical procedures, are not performed with the target tissue submerged under an irrigant. In laparoscopic procedures, such as the mesculon of the gall bindder from the liver, for example, the abdominal cavity is pressurized with carbon dioxide (pneumoperitoneum) to provide working space for the instruments and to improve the surgeon's visibility of the surgical site. Other procedures, such as the ablation of muscle or giagiva tissue in the mouth, the ablation and necrosis of diseased tissue, or the ablation of epidermal tissue, are also typically performed in a "thy" environment or field (i.e., not submerged under an electrically conducting irrigant).

Present electrosurgical techniques used for tissue abiation also suffer from an insbility to control the depth of accrosis in the tissue being treated. Most electrosurgical devices rely on creation of an electric are between the treating electrode and the tissue being cut or ablated to cause the desired localized heating. Such arcs, however, often create very high temperatures causing a depth of accrosis greater than 500 µm, frequently greater than 500 µm, and sometimes as great as 1700 µm. The inability to control such depth of accrosis is a significant disadvantage in using electrosurgical techniques for tissue ablation, particularly in arthroscopic procedures for ablating and/or reshaping fibrocartilage, articular cartilage, meniscal tissue, and the like.

In an effort to overcome at least some of these limitation of electrosurgery, laser apparatus have been developed for use in arthroscopie and other procedures. Lasers do act suffer from electrical shorting in conductive environments. and certain types of lasers allow for very controlled cutting with limited depth of accresis. Despite these advantages. laser devices suffer from their own set of deficiencies. In the first place, laser equipment can be very expensive because of the costs associated with the laser light sources. Moreover those lasers which permit acceptable depths of accrosis (such as eximer lasers, erbium:YAG lasers, and the like) provide a very low volumetric ablation rate, which is a particular disadvantage in cutting and abiation of abrocartilage, articular cartilage, and maniscal tissue. The bolmium:YAG and NeYAG lasers provide much higher volumetric abiation rates, but are much less abie to or depth of accrosis than are the slower laser devices. The CO2 lasers provide high rate of ablation and low depth of tissu necrosis, but cannot operate in a liquid-filled cavity.

For these and other reasons, improved systems and methods are desired for the electrosurgical ablation and cutting of

tissue. These systems and methods should be expable of selectively cutting and ablating tissue and other body structures in electrically conductive environments, such as regions filled with blood or irrigated with electrically conductive solutions, such as isotonic saline, and in relatively 5 dry environments, such as those encountered in oral, dermatological, laparoscopic, thoracosopic and open surgical procedures. Such apparatus and methods should be able to perform cutting and ablation of tissues, while limiting the depth of necrosis and limiting the damage to tissue adjacent 10 to the treatment tike.

DESCRIPTION OF THE BACKGROUND ART

Devices incorporating radio frequency electrodes for use in electrosurgical and electrocautery techniques are described in Rand et al. (1985) J. Arshro. Surg. 1:242-246 and U.S. Pal. Nos. 5-281-216; 4.943-290; 4.936-301; 4.593, 691; 4.728.800; and 4.202-337. U.S. Pal. Nos. 4.943-290 and 4.036-301 describe methods for injecting non-conducting liquid over the tip of a monopolar electrosurgical electrode to electrically isolate the electrode, while energized, from a surrounding electrically conducting irrigant. U.S. Pat. Nos. 5.195-959 and 4.574,499 describe monopolar and bipolar electrosurgical devices, respectively, that include a conduit for irrigating the surgical site.

U.S. Pat. Nos. 5.217.455, 5.423.803, 5.102.410, 5.282, 797, 5.290.273, 5.304.170, 5.312.395, 5.336.217 describe laser treatment methods for removing abnormal skin cells, such as pigmentations, lesions, soft tissue and the life. U.S. Pat. Nos. 5.445.634 and 5.370.662 describe methods for using laser eaergy to divide, incise or resect tissue during cosmetic surgery, U.S. Pat. No. 5.261.410 is directed to a method and apparatus for detecting and removing malignant lumor tissue, U.S. Pat. Nos. 5.360.316, 4.658.817, 5.389, 096, PCT application No. WO 94/14383 and Buropean Patent Application No. 0 515 867 describe methods and apparatus for percutaneous myocardial revascularization. These methods and apparatus involve directing laser eaergy against the heart tissue to form transverse channels through the myocardium to increase blood flow from the ventricular cavity to the myocardium.

SUMMARY OF THE INVENTION

The present invention provides a system and method for 45 selectively applying electrical energy to structures within or on the surface of a patient's body. The system and method allow the surgical team to perform electrosurgical interventions, such as ablation and cutting of body structures, while limiting the depth of necrosis and limiting damage to tissue adjacest the treatment site. The system and method of the present invention are useful for surgical procedures in relatively dry environments, such as treating and shaping gingive, for tissue dissection, e.g. separation of gall bladder from the liver, ablation and necrosis of diseased as tissue, such as fibroid tumors, and dermatological procedures involving surface tissue abiation on the epiden such as sour or tattoo removal, tissue rejuvenation and the like. The present invention may also be useful in electrically conducting environments, such as arthroscopic or cystoscopic surgical procedures. In addition, the present invention is useful for canalizing or boring channels or holes through tissue, such as the ventricular wall of the heart during transmyocardial revascularization procedures

The method of the present invention comprises positioning an electrosurgical probe adjacent the target tissue so that at least one active electrode is brought into close proximity

to the target site. A return electrode is positioned within an electrically conducting liquid, such as isotonic saline, to generate a current flow path between the target site and the renum electrode. High frequency voltage is then applied between the active and return electrode through the current flow path created by the electrically conducting liquid in either a bipolar or monopolar manner. The probe may then be translated, reciprocated or otherwise manipulated to cut the tissue or effect the desired depth of abiation.

The current flow path may be generated by submerging the tissue site in an electrical conducting fluid (e.g., arthr scopic surgery and the like) or by directing an electrically conducting liquid along a fluid path past the return electrode and to the target site to generate the current flow path between the target site and the return electrode. This latter method is particularly effective in a dry environment (i.e., the tissue is not submerged in fluid), such as open, endoscopic or oral surgery, because the electrically conducting liquid provides a suitable current flow path from the target site to the seturn electrode. The active electrode is preferably disposed at the distal end of the probe and the return trode is spaced from the active electrode and enclosed within an inculating sheath. This minimizes exposure of the return electrode to surrounding tissue and minimizes possible shorting of the current between the active and set electrodes. In oral procedures, the probe may be introduced directly into the cavity of the open mouth so that the active electrode is positioned against gingival or mucosal tissue. In endoscopic procedures, the probe will typically be passed through a conventional tracer cannula while viewing of the operative site is provided through the use of a laparoscupe disposed in a separate canania.

In a specific aspect of the invention, the high frequency voltage applied between the active and return electrodes generates high voltage gradients in the vicinity of the probe tip. These high voltage gradients in the vicinity of the probe electric field at the distal boundary of the active electrode(s) that is sufficiently high to break down the tissue through molecular dissociation or distinguished. The high frequency voltage imparts energy to the target she to ablate a thin layer of tissue without causing substantial tissue necrosis beyond the boundary of the thin layer of tissue ablated. This ablative process can be precisely controlled to effect the volumetric removal of tissue as thin as a few layers of cells with minimal besting of or damage to surrounding or underlying tissue structures.

Applicants believe that this precisely controlled able is at least partly caused by the high electric field generate around the tip of the active electrode(s) within the electrically conductive liquid. The electric field vaporizes the electrically conductive liquid into a thin layer over at least a portion of the active electrode surface and then ionizes the vapor layer due to the presence of an ionizable species within the liquid. This ionization and the presence of high electric fields in a low density vaporized layer induces the discharge of highly energetic electrons and photons in the form of nitraviolet energy from the vapor layer. The ultr violet energy and/or energetic electrons cause disintegration of the tissue molecules adjacent to the vapor layer. This energy discharge can be precisely controlled to effect the ohimenic removal of tissue thicknesses ranging from millimeters to a few layers of cells without heating or otherwise damaging surrounding or underlying cell structures.

The active electrode(s) will be spaced away from the turget tissue by a suitable distance during the abiation process. This spacing allows for the continual resupply of electrically conducting liquid at the interface between the active electrode(s) and the target tissue surface. This continual resupply of the electrically conducting liquid helps to ensure that the thin vapor layer or region will remain over at least a portion of the active electrode(s) between the active electrode(s) and the tissue surface. Preferably, the active electrode(s) will be translated and/or rotated transversely relative to the tissue. I.e., in a light brushing motion, to maintain the supply of electrically conducting fluid in the region between the active electrode(s) and the tissue. This dynamic movement of the active electrode(s) over the tissue 100 site also allows the electrically conducting liquid to cool the tissue surrounding recently ablated areas to minimize damage to this surrounding tissue.

The apparatus according to the present invention comprises an electrosurgical probe having a shaft with a proximal end, a distal end, and at least one active electrode at or near the distal end. A connector is provided at or near the proximal end of the shaft for electrically coupling the active electrode to a high frequency voltage source. A return electrode coupled to the voltage source is spaced a sufficient 20 distance from the active electrode to substantially avoid or minimize current shorting therebetween and, in dry environments, to shield the return electrode from tissue at the target site of ablatica or from the surgeon. In irrigant flooded cavironments, such as arthroscopic surgery, the area 25 supply of FIG. 1; of the return electrode is sufficiently large to result in low current densities that effectively preclude damage to nearby tissue. The return electrode may be provided integral with the shaft of the probe or it may be separate from the shaft (e.g., on a liquid supply incrument). In both cases, the return to electrode defines an inner, annular surface of the pathway for flow of electrically conducting liquid therethrough. The liquid is directed past the surface of the return electrode and over the active electrode to thereby provide a return current flow path between the target tissue site and the return as

The active and return electrodes will preferably be configured such that, upon the application of a sufficient highfrequency voltage, a thin layer of the electrically conducting layer is vaporized over at least a portion of the active electrode(s) in the region between the active electrode(s) and the target tissue. To accomplish this, the active electrode(s) will be configured such that high electric field densities form at the distal tips of the active electrode(s). By way of example, the present invention may utilize an electrode array as of electrode terminals flush with or roccessed from or exten ing from the distal end of the probe. The electrode terminals will preferably have a sufficiently small area, extension (or recession) length from the probe and sharp edges and/or surface asperities such that localized high current densities are promoted on the electrode terminals which, in turn, lead to the formation of a vaporized layer or region over at least a portion of the active electrode(s) followed by the high electric field induced breakdown (i.e., ionization) of io able species within the vapor layer or region and the ss emission of photon and/or electrons of sufficient energy to cause dissociation of molecules within the target tissue.

Is an exemplary embodiment, the active electrode(s) are sized and arranged to create localized sources of energy (e.g., point sources or sources with a relatively small effective radius) at the distal tips of the electrode(s) whos a sufficiently high frequency voltage is applied to the return and active electrodes. These small localized sources generate intense energy at the distal ends of the electrodes for molecular dissociation or ablation of tissue in consect with or in close proximity so the electrode tips. In addition, since the localized sources have relatively small radii, the energy

flux docreases with the square of the distance from the localized sources so that the tissue at greater distances from the electrode tips are not significantly affected by the energy

A further understanding of the nature and advantages of the invention will become apparent by reference to the remaining portions of the specification and drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of the electrosurgical system including an electrosurgical probe, an electrically conducting flquid supply and an electrosurgical power supply constructed in accordance with the principles of the present invention:

FEG. 2A is an enlarged, cross-sectional view of the distal tip of the electrostrajical probe of FIG. I illustrating an electrode arrangement suitable for rapid cutting and ablation of tissue structures;

FIG. 2B is an enlarged end view of the distal tip of the electromylical probe of FIG. 1;

FIG. 2C is a cross-sectional view of the proximal end of the electrosurgical probe, illustrating an arrangement for coupling the probe to the electrically conducting liquid supply of PIG. 1:

FIG. 3 is a detailed cross-sectional view of an alternative embodiment of the electrosurgical probe of FIG. 1;

FIG. 4 is an end view of the distal end of the electrowargical probe of FIG. 3;

PIG. 5 is an end view of an another embodiment of the electrosurgical probe of PIG. 1;

FIG. 6 is a partial cross-sectional side view of a further embodiment of the electromagical probe with the electrode array disposed transversely to the axis of the probe;

PIG. 7 is a perial frost cross-sectional view of an electroscopical probe and an electrically conductive liquid supply shaft libestrating use of the probe and the shaft in abiliting target tissue;

FIG. 8 is an enlarged, cross-sectional view of the distal tip of yet another embodiment of the electrosurgical probe of FIG. 1;

FIG. 9 is a detailed end view of the probe of FIG. 8;

5 PIG. 10 is a side view of an electrosurgical probe having a shaft with an engled distal portion;

PRG. 11 is a side view of an electrosurgical probe having a shaft with a perpendicular distal postion;

FKI. 12 is a schematic view of an electrosurgical probe to baving two accessives shaped electrodes extending from the disal and;

FIG. 13 is an ead view of the probe of FIG. 12;

FIG. 14 likestrates use of the probe of FIG. 12 for the rapid cutting of these;

PSG. 15 is a cross-sectional view of the distal tip of the electrosurgical probe, illustrating electric field lines between the active and return electrodes;

FIG. 16 is an enlarged cross-sectional view of the distal tip of the probe of FIG. 15, illustrating a vapor layer formed between the active electrodes and the target tissue;

FIG. 17 is a cross-sectional view of an alternative electrostrigical probe for applying high frequency voltage to epidermal tissue layers;

FIG. 18 is a sectional view of the human heart, illustrating the electrosurgical probe while the ventricular cavity for performing a transmyocardial revescularization procedure; FRG. 19 is a cross-sectional view of the probe boring a channel through the vestricular wall;

FEG. 20 depicts an alternative embodiment of the probe of FIG. 19 having an inner lunes for aspirating fluid and gases from the transmyocardial channel;

FIG. 21 depicts a distal portion of an alternative embodiment of the probe of FIGS, 2A-2C incorporating a single electrode with a tubular geometry;

FIG. 22 is a cross-sectional view of the distal end of the probe of FIG. 21;

FIG. 23 is a side cross-sectional view of a distal parties of a further embodiment of the probe of FIGS. 2A-2C incorporating a multiplicity of electrodes which coaverge to a single electrode lead; and

FIG. 24 is a side cross-sectional view of a distal portion of yet another embodiment of the probe of FIGS. 2A-3C incorporating a single electrode coanceted to a single electrode lead.

DESCRIPTION OF THE PREFERRED EMBODIMENT

The present invention provides a system and method for selectively applying electrical energy to a target location within or on a patient's body, such as solid tissue or the like, 23 perticularly including gingival tissues and mucocal tissue located in the mouth or spidermal tissue on the outer side In addition, tissues which may be treated by the system and method of the present invention include numers, abnormal dissues, and the like. The invention may also be used for $_{20}$ canatizing or boring channels or holes through tissue, such as the ventricular wall during transmyocardial sevascula ization procedures. For convenience, the semaining disclo sure will be directed specifically to the cutting, shaping or ablation of gingival or mucosal tissue in oral surgical procedures, the surface tissue ablation of the epidermis in dermatological procedures and the canalization of chancels through the myocardism of the heart, but it will be apprecitted that the system and method can be applied eq well to procedures involving other tissues of the body, at well as to other procedures including open surgery, lapuroscopic surgery, thosacoscopic surgery, and other endoscopic surgical procedures.

In addition, the present invention is particularly useful in procedures where the dissue site is flooded or submerged at with an electrically conducting fluid, such at isotonic ratine. Such procedures, e.g., arthrotopic surgery and the like, are described in detail in co-pending PCT international Application, U.S. National Phase Serial No. PCT/US94/05168, filed on May 10, 1994, the complete disclosure of 50 which has been incorporated herein by reference.

The present invention may use a single active electrods or an electrode array distributed over a distal contact surface of a probe. The electrode array timally includes a pinrality of independently current-limited and/or power-controlled electrode terminals to apply electrical energy selectively to the target sissue while limiting the unwanted application of electrical energy to the surrounding tissue and environment resulting from power distipation into surrounding electrically conductive liquids, such as blood, normal saline, and so the liths. The electrode terminals may be independently current-limited by isolating the terminals from each other and connecting each terminal to a separate power source that is isolated from the other electrode terminals. Alternatively, the electrode terminals may be connected to each other at estimate the precision of distal ends of the probe to form a single wire that couples to a power source.

8

The electrosurgical probe will comprise a shaft having a proximal end and a distal end which supports an active electrode. The shift may assume a wide variety of configurations, with the primary purpose being to mechanically support the active electrode and permit the treating physician to manipulate the electrode from a proximal end of the shaft. Usually, the shaft will be a narrow-diameter sed or tube, more usually baving dimensions which permit it to be introduced into a body cavity, such as the mouth or the abdominal cavity, through an associated trocar or canania in a minimally lavasive procedure, such as arthroscopic, Isparoscopic, thoracoscopic, and other endoscopic procedures. Thus, the shaft will typically have a length of at least 5 cm for oral procedures and at least 10 cm, more typically being 20 cm, or longer for codoscopic procedures. The shaft will typically have a diameter of at least 1 mm and froqueatly in the range from 1 to 10 mm. Of course, for dermaiological procedures on the outer skin, the shaft may have any suitable length and diameter that would facilitate handling by the surgeon.

The shaft may be rigid or flexible, with flexible shafts optionally being combined with a generally rigid external tube for mechanical support. Flexible shafts may be combined with pull wises, shape memory actuators, and other known mechanisms for effecting selective deflection of the distal end of the shaft to facilities positioning of the electrode array. The shaft will usually include a plurality of wises or other conductive elements musaing axially therethrough to permit connection of the electrode array to a connector at the proximal end of the shaft. Specific shaft designs will be described in detail in connection with the figures beningther.

The circumscribed area of the electrode array is in the range from 0.25 mm² to 75 mm², preferably from 0.5 mm². to 40 mm2, and will usually include at least two isolated electrode terminals, more usually at least four electron terminals, preferably at least six electrode terminals. as often 50 or more electrode terminals, disposed over the distal contact surfaces on the shaft. By bringing the electrode array(s) on the contact surface(s) in close proximity with the target tissue and applying high frequency voltage between the array(s) and an additional common or return electrode in direct or indirect costact with the patient's body, the target tissue is selectively ablated or cut, permitting selective movel of portious of the target tissue while desirably minimizing the depth of necrods to surrounding these. In particular, this invention provides a method and apparatus for effectively ablating and cutting tissue which may be located in close preximity to other critical organs, vessels or structures (e.g., teeth, bone) by simultaneously (1) causing electrically conducting Equid to flow between the common and active electrodes. (2) applying electrical energy to the target tissue surrounding and immediately adjacent to the tip of the probe. (3) bringing the active electrodo(s) is close proximity with the target tissue using the probe itself, and (4) optionally moving the electrode array axially and/or treasrenely over the home.

In one configuration, each ladividual electrode terminal in the electrode army is electrically insulated from all other electrode terminals in the army within said probe and is connected to a power source which is isolated from each of the other electrodes in the army or to circuitry which limits or interrupts current flow to the electrode when low resistivity material (e.g., blood or electrically conductive sailne irrigant) causes a lower impedance path between the common electrode and the individual electrode terminal. The isolated power sources for each individual electrode may be separate power supply circuits having internal impoduance

characteristics which limit power to the associated electrode terminal when a low impedance reura path is exconsered, may be a single power source which is connected to each of the electrodes through independently actuable switches or may be provided by independent current limiting elements, such as inductors, capacitors, resistors and/or combinations thereof. The current limiting elements may be provided in the probe, connectors, cable, controller or along the conductive path from the controller to the distail tip. Alternatively, the resistance and/or especitance may occur on the surface of the active electrode(s) due to oxide layers which form selected electrode terminals (e.g., timaium or a resistive coating on the surface of metal, such as platinum)

The tip region of the probe may be composed of man independent electrode terminals designed to deliver electrical energy is the vicinity of the tip. The selective application of electrical energy to the target those is achieved by connecting each individual electrode terminal and the co mos electrode to a power source having independently controlled or current limited channels. The common elecwode may be a tubular member of conductive meterial proximal to the electrode array at the tip which also serves as a conduit for the supply of the electrically conducting liquid between the active and common electrodes. The application of high frequency voltage between the common lectrode and the electrode axxy results in the generation of high electric field intensities at the distal tips of the eleces with conduction of high frequency current from each individual electrode terminal to the common electrode. The current flow from each individual electrode terminal to the 20 common electrode is controlled by either active or passive means, or a combination thereof, to deliver electrical energy means, or a communication unada, and are energy delivery to
to the target tissue while minimizing energy delivery to crounding (non-target) tissue and any conductive fi which may be present (e.g., blood, electrolytic infigures such as saline, and the like).

In a preferred aspect, this invention takes advantage of the differences in electrical resistivity between the target tissue (e.g., giagiva, muncle, fascia, tumor, spidermal, heart or other tissue) and the surrounding conductive Equid (e.g., isotonic saline irrigant). By way of example, for any selected level of applied voltage, if the electrical condu e common electrode and one of the individual electrode terminals within the electrode agray is isotonic saline irrigant liquid (having a relatively low electrical impedance), the current control means connected to the individual electrode will limit current flow so that the heating of intervening conductive liquid is minimized. On the other hand, if a portion of or all of the electrical conduction path between the common electrode and one of so al electrode terminals within the electrode acres is gingival tissue (having a scietively higher electrical impedance), the current control circulty or switch con-nected to the individual electrode will allow current flow sufficient for the deposition of electrical energy and associated ablation or electrical breakdown of the target tissue in the immediate vicinity of the electrode surface

The application of a high frequency voltage between the common or return electrode and the electrode array for appropriate time intervals effects abistion, coming or restaying of the target tissue. The tissue voltane over which energy is dissipated (i.e., a high voltage gradient exists) may be precisely controlled, for example, by the use of a multiplicity of small electrodes whose effective diameters range from about 2 mm to 0.01 mm, preferably from about 1 mm to 0.03 mm, and more preferably from about 0.5 mm to 0.1 mm. Electrode areas for both circular and non-circular terminals

will have a contact area (per electrode) below 5 mm³, preferably being in the range from 0.0001 mm² to 1 mm³, and more preferably from 0.005 mm³ to 0.5 mm². The use of small dismeter electrode terminals increases the electric field intensity and soduces the extent or depth of tissue necrosis as a consequence of the divergence of current flux lines which emanate from the exposed surface of each electrode terminal. Bargy deposition in tissue sufficient for inverteable damage (i.e., necrosis) has been found to be limited to a distance of about one-half to one electrode diameter. This is a particular advantage over prior electrosurgical probes employing single and/or larger electrodes where the depth of distance accrosis may not be sufficiently limited.

In previous electrosurgical devices, increased power application and ablation rates have been achieved by increasing the electrode area. Surprisingly, with the present invention, it has been found that the total electrode area can be increased (to increase power delivery and abiation rate) without increasing the depth of necrosis by providing mus-sinks small electrode terminals. Preferably, the terminals will be spaced-spart by a distance in the range from about one-half diameter to one diameter for optimum power delivery, as discussed below. The depth of accrosis may be further controlled by switching the applied voltage off and on to produce pulses of current, the pulses being of sufficient duration and associated energy density to effect ablation and/or cutting while being turned off for periods sufficiently ong to allow for thermal relaxation between energy pulses. In this meaner, the energy pulse duration and magnitude and the time interval between energy pulses are selected to achieve efficient rates of tissue abintion or cutting while allowing the temperature of the treated zone of tissue to "relat" or setura to normal physiologic temperatures (usually to within 10° C. of normal body temperature [37° C.], preferably to within 5° C.) before the onset of the next escrift (conscat) pulse.

In addition to the above described methods, the applicant has discovered another mechanisms for ablating tissue while minimizing the depth of necrosis. This mechanism involves applying a high frequency voltage between the active electrode surface and the means electrode to develop high electric field intensities in the vicinity of the target tissue size. The high electric field intensities load to electric field induced molecular healthown of target tissue strough molecular dissociation (rather than thermal evaporation or entonization). In other words, the tissue structure is volumetrically removed through molecular disintegration of complex organic molecular into non-visible atoms and molecules, such as hydrogen, exides of carbon, hydrocurbons and altrogen compounds. This molecular, as opposed to transforming the tissue material from a solld form directly to a vapor form, as is typically the case with shistion.

The high electric field intensities may be generated by applying a high frequency voltage that is sufficient to vaporitie the electrically conducting liquid over at least a portion of the active electrode(a) in the region between the district the vapor layer or vaporitied region has a relatively high electrical impedance, it increases the voltage differential between the active electrode tip and the tissue and causes ionization within the vapor layer due to the presence of an ionization within the vapor layer due to the presence of an ionizable species (e.g. actium when isotonic saline is the electrically conducting field). This ionization, under optimal conditions, induces the discharge of energetic electrons and photons from the vapor layer and to the surface of the target

tissue. This energy may be in the form of energetic photons (e.g., ultraviolet radiation), energetic particles (e.g., electrons) or a combination thereof.

The accessary conditions for forming a vapor layer ness the active electrode tip(s), ionizing the stom or atoms within the vapor layer and inducing the discharge of energy from plasma withis the vapor layer will depend on a variety of factors, such as: the number of electrode terminals; electrode size and spacing; electrode surface area; asperities and sharp edges on the electrode surfaces; electrode materials; applied voltage and power; current limiting means, such as inductors; electrical conductivity of the fluid in contact with the electrodes; density of the fluid; and other factors. Based on initial experiments, applicants believe that the icalization of atoms within the vapor layer produced is isotosic saline (containing sodium chloride) leads to the generation of energetic photons having wavelengths, by way of example, in the range of 306 to 315 nanometers (ultraviolet specuram) and 588 to 590 amometers (visible spectrum). In addition the free electrons within the ionized vapor layer are accelcrated in the high electric fields near the electrode tip(e). 20 When the density of the vapor layer (or within a babble formed in the electrically conducting liquid) becomes suf-ficiently low (i.e., less than approximately 10²⁰ atoms/cm² our solutions), the electron mean free path increases to enable subsequently injected electrons to cause impact ionization within these regions of low density (i.e., vapor layers or bubbles). Paerry evolved by the energetic clostross (e.g., 4 to 5 eV) can subsequently bombard a molecule and break its bonds, dissociating a molecule into free radicals, which then combine into final gascous or liquid 30

The photon energy produces photonbistion through photon cochemical and/or photonbermal processes to disintegrate tissue thicknesses as small as several cell layers of tissue at the target site. This photon bis a "cold" ablation, which means that the photon energy transfers very little heat to tissue beyond the boundaries of the region of tissue ablated. The cold ablation provided by photon energy can be precisely controlled to only affect a this layer of cells without heating or otherwise damaging surrounding or underlying cells. The depth of necrosis will be typically a about 0 to 400 microns and usually 10 to 200 microns. Applicants believe that the "fragments" of disintegrated tissue molecules carry away much of the energy which is deposited on the surface of the target tissue, thereby allowing molecular disintegration of tissue to occur while limiting the amount of heat transfer to the surrounding tissue.

In addition, other competing mechanisms may be contributing to the ablation of tissue. For example, tissue destruction or ablation may also be caused by dielectric to breakdown of the tissue structural elements or cell membranes from the highly concentrated batense electric fields at the tip portions of the electrode(s). According to the teachings of the present invention, the active electrode(s) are sized and have exposed surfaces are as which, under proper conditions of applied voltage, cause the formation of a vaporized region or layer over at least a portion of the surface of the active electrode(s). This layer or region of vaporized electrically conducting liquid creates the conditions accessary for ionization within the vaporized region or to layer and the generation of susceptic electrons and photons. In addition, this layer or region of vaporized electrically conducting liquid provides a high electrical impedance between the electrode and the adjacent tissue so that only low levels of current flow across the vaporized layer or 45 region into the tissue, thereby minimizing jouless heating is, and associated necrosis of, the tissue.

As discussed above, applicants have found that the dea-sity of the electrically conducting liquid at the distai tips of the active electrodes should be less than a critical value to form a suitable vapor layer. For aqueous solutions, such as water or isotonic saline, this upper density limit is approxi-mately 10²⁰ atoms/cm², which corresponds to about 3×10⁻⁴ grams/cm³. Applicant's also believe that once the deasity in the vapor layer reaches a critical value (e.g., approximately 10²⁰ atoms/cm² for aqueous solutions), electron avalanche occurs. The growth of this avaluache is retarded when the space charge generated fields are on the order of the external field. Spatial extent of this region should be larger than the distance required for an electron avalanche to become critical and for an ionization front to develop. This ionization front develops and propagates across the vapor layer via a sequence of processes occurring in the region ahead of the front, viz. heat by electron injection. lowering of the local liquid density below the critical value and avalanche growth of the charged particle concentration.

Electrons accelerated in the electric field within the vapor layer will apparently become trapped after one or a few scatterings. These injected electrons serve to create or sustain a low density region with a large mean free path to enable subsequently injected electrons to cause impact ionization within these regions of low density. The energy evolved at each recombination is on the order of half of the energy band gap (i.e., 4 to 5 eV). It appears that this energy can be transferred to another electron to generate a highly energetic electron. This second, highly energetic electron may have sufficient energy to bembard a molecule to break its boads, i.e., dissociate the molecule into free radicals.

The electrically conducting liquid should have a threshold conductivity in order to suitably ionize the vapor layer for the indocement of energetic electrons and photons. The electrical conductivity of the fluid (in units of milliSies per centimeter or mS/cm) will assuilly be greater than 0.2 mS/cm, preferably will be greater than 2 mS/cm and more preferably greater than 10 mS/cm. In an exemple the electrically conductive fluid is in saline, which has a conductivity of about 17 mS/c electrical conductivity of the channel trailing the joulze front should be sufficiently high to maintain the energy flow required to heat the liquid at the ionization from maintain in density below the critical level. In addition when the electrical conductivity of the liquid is sufficient high, jonic pre-breakdown current lovels (i.e., carrent lovels prior to the lahintion of ionization within the vapor layer) are sufficient to also promote the initial growth of buildies within the electrically conducting liquid (i.e., regions whose density is less than the critical density).

Aspesties on the surface of the active electrode(s) appear to promote localized high current densities which, in promote bubble nucleation at the site of the asperties whose caclosed density (i.e., vapor density) is below the critic density to inkinte louization breakslows within the bubble wa within the bubble. Hence, a specific configuration of the present invention as of high courent dessities on the tips of the creases regio electrode(s) (i.e., the surface of the electrode(s) which are to cagage and ablate or cut tissue). Regions of high current densities can be achieved via a variety of methods, such as producing therp edges and corners on the distal tips of the electrodes or vapor blasting, chemically exching or mechanically abrading the distal end faces of the active electrodes to produce surface asperitles thereon. Alternatively, the electrode terminals may be specifically designed to increase the edge/surface area ratio of the electrode terminals. For example, the electrode terminal(s) may be hollow tebes

having a distal, circumferential edge surrounding an opening. The terminals may be formed in an array as described above or in a series of concentric terminals on the distal end of the probe. High current densities will be generated around the circumferential edges of the electrode terminals to promote nucleuse bubble formation.

The voltage applied between the common electrode and the electrode array will be at high or radio frequen typically between about 5 kHz and 20 MHz. ascally being between about 30 kHz and 2.5 MHz, and preferably being between about 50 kHz and 400 kHz. The RMS (root mean square) voltage applied will estably be in the range from about 5 volts to 1000 volts, preferably being in the range from about 50 volts to 800 volts, and more preferably being in the range from about 100 volts to 400 volts. These 15 frequencies and voltages will result in peak-to-peak voltages and currents that are sufficient to vaporize the electrically conductive liquid and, in turn, create the conditions within the vaporized region which result in high electric fields and emission of energetic photons and/or electrons to ablate an tissue. Typically, the peak-to-peak voltage will be in the range of 200 to 2000 volts and preferably in the range of 300 to 1400 volts and more preferably in the range of 700 to 900

As discussed above, the voltage is usually delivered in a series of voltage pulses with a sufficiently high frequency (e.g., on the order of 5 LHz to 20 MHz) such that the voltage is effectively applied continuously (as compared with e.g., lasers claiming small depths of accrosis, which are generally pulsed about 10 to 20 Hz). In addition, the pulsed duty cycle (i.e., cumulative time in any one-second interval that energy is applied) is on the order of about 50% for the present invention, as compared with lasers which typically have a duty cycle of about 0.0001%.

Applicants believe that the present invention is capable of obtaining high ablation rates with effectively continuous mode operation and high duty cycles because the source of energy emitted from the edges and tips of the small electrode terminals is effectively a point source or a source having a relatively small effective radies. As is well known in the art, so the flux emitted from a point source and crossing a boundary in spherical space generally decreases as the square of distance from the source. Thus, the "energy source" of the present invention (i.e., the latense electric field, the energetic photons or the energetic electrons) is highly concentrated by virtue of the geometry of the emitting electrodes and the source of energy at the tips of the electrodes. As a result, only those regions or areas that are very close to the electrode tips or source will be exposed to high energy fluxes. Consequently, ablation will typically only occur in so tissue layers effectively in contact or in very close proximity with the tips of the electrodes. The tissue at greater distances from the electrode tips are not significantly affected since the energy flux is too low at these distances to inveversibly affect or damage tissue.

Usually, the current level will be selectively limited or controlled and the voltage applied will be independently adjustable, frequently in response to the resistance of tissues and/or fluids in the pathway between an individual electrode and the common electrode. Also, the applied current level may be in response to a temperature control means which maintains the target tissue temperature with desired limits at the interface between the electrode arrays and the target tissue. The desired tissue temperature along a propagating surface juit beyond the region of ablation will usually be in the range from about 40° C, to 100° C, and more usually from about 50° C, to 60° C. The tissue being ablated (and

hence removed from the operation site) immediately adjacent the electrode array may reach even higher temperatures.

The preferred power source of the present invention delivers a high frequency current selectable to generate average power levels ranging from seas of milliwarm to teas of watts per electrode, depending on the target dissue being ablated, the rate of ablation desired or the maximum allowed temperature selected for the probe tip. The power source allows the user to select the current level according to the specific requirements of a particular oral surgery, dermatological procedure, open surgery or other endoscopic surgery procedure.

The power source may be current limited or otherwise controlled so that undesired beating of electrically conductive fluids or other low electrical resistance media does not occur. In a presently preferred embodiment of the present invention, current limiting inductors are placed in series with each independent electrode terminal, where the inductance of the inductor is in the range of 10 wH to 50,000 wH. depending on the electrical properties of the target tissue, the desired ablation rate and the operating frequency. Alternatively, expector-inductor (LC) circuit structures may be employed, as described previously in co-pending PCT application No. PCT/US94/05168, the complete disclosure of which is incorporated herein by reference. Additionally, current limiting resistors may be selected. Preferably, the resistors will have a large positive temperature coefficient of resistance so that, as the current level begins to rise for any individual electrode in contact with a low resistance a (e.g., saline irrigant), the resistance of the current limitin resistor increases significantly, thereby minimizing the power delivery from said electrode into the low resistant medium (e.g., saline irrigant).

medium (e.g., taline krigant).

As as alternative to such passive circuit structures, regisized current flow to each electrode terminal may be provided by a mutti-channed power supply. A substantially constant current level for each individual electrode terminal within a range which will limit power delivery through a low resistance path, e.g., isotonic saline irrigant, and would be selected by the user to achieve the desired rate of cutting exhibition. Such a multi-channel power supply thus prevides a substantially constant current source with selectable current level in series with each electrode terminal, wherein all electrode will operate at or below the same, user selectable maximum current level. Current flow to all electrode terminals could be periodically seased and stopped if the temperature measured at the surface of the electrode entry exceeds user selected limits. Particular control system designs for implementing this strategy are well within the still of the art.

Yet another alternative involves the use of one or several power supplies which allow one or several electrodes to be simultaneously energized and which include active control means for limiting current levels below a preselected markinum level. In this arrangement, only one or several electrodes would be simultaneously energized for a brief period. Switching means would allow the acts one or several electrodes to be energized for a brief period. By sequentially energizing one or several electrodes, the interaction between adjacent electrodes can be minimized (for the case of energizing several electrode positioned at the maximum possible spacing whilm the overall envelope of the electrode array) or eliminated (for the case of energizing only a single electrode at any one time). As before, a resinance measurement means may be employed for each electrode prior to the application of power wherein a (measured) low resinance (below some preselected level) will prevent that electrode

from being energized during a given cycle. By way of example, the sequential powering and control scheme of the present invention would function in a manner similar to an automobile distributor. In this example, an electrical contact rotates past terminals connected to each spark plug. In this example, each spark plug corresponds to the exposed surface of each of the electrodes. In addition, the present invention scludes the means to measure the resistance of the medium in contact with each electrode and cause voltage to be applied only if the registance exceeds a presclected level.

It should be clearly understood that the invention is not limited to electrically isolated electrode terminals, or even to a plurality of electrode terminals. For example, the array of active electrode terminals may be connected to a single lead that extends through the probe shaft to a power source of high frequency current. Alternatively, the probe may income porate a single electrode that extends directly through the probe shaft or is connected to a single lead that extends to

The active electrode(s) are formed over a contact surface 20 on the shaft of the electromygical probe. The common (return) electrode surface will be recessed relative to the distal end of the probe and may be recessed within the conduit provided for the introduction of electrically conducting liquid to the site of the target dasus and active electrode(s). In the exemplary embodiment, the shaft will be cylindrical over most of its length, with the contact surface being formed at the distal end of the shaft. In the case of endoscopic applications, the contact surface may be recessed since it belos protect and shield the electrode 30 terminals on the surface while they are being introduced, particularly while being introduced through the working channel of a trocar channel or a viewing scope.

The area of the contact surface can vary widely, and the contact surface can assume a variety of geometries, with particular areas in geometries being scheded for specific applications. Active electrode contact surfaces can have approximate. Active electrone country attracts can have areas in the range from 0.25 mm² to 50 mm², usually being from 1 mm² to 20 mm². The geometries can be planer, concave, convex, hemispherical, conicsi, linear "in-line" array or virtually any other regular or irregular shape. Most only, the active electrode(s) will be formed at the distal tip of the electrosurgical probe shaft, frequently being planer, disk-shaped, or hemispherical surfaces for use in remaples procedures or being linear arrays for use in as cutting. Alternatively or additionally, the active electrode(s) may be formed on laural surfaces of the electrosurgical probe that (e.g., in the manner of a spatula), facilitating access to extain body structures in electrosurgical proce-

During the surgical procedure, the distal end of the probe or the active electrode(s) will be maintained at a small distance away from the target tissue surface. This small spacing allows for the continual resupply of electrically conducting liquid into the intenface between the active 35 electrode(s) and the target tissue surface. This cost resupply of the electrically conducting liquid helps to east that the this vapor layer will remain between active electrode(s) and the tissue surface. In addition, dynamic movement of the active electrode(s) over the tissue site of allows the electrically conducting Equid to cool the tissue amousting secently ablated areas to minimize thermal damage to this surrounding tissee. Typically, the active electrode(s) will be about 0.02 to 2 mm from the target tissue s. One method of maintaining this space is to translate and/or rotate the probe transversely relative to the tissue, i.e.,

a light brushing motion, to maintain a thin vaporized layer or region between the active electrode and the tissue. Of course, if coagulation of a deeper region of tissue is necessary (e.g., for sealing a bleeding vessel imbedded within the tisme), it may be desirable to press the active electrode against the tissue to effect joulean beating therein.

Referring to the drawings in detail, wherein like numerals indicate like elements, as electrosurgical system 11 is shown constructed according to the principles of the present invention. Electrosurgical system 11 generally comprises an electrosurgical probe 10 connected to a power supply 28 for providing high frequency voltage to a target tissue 52 and a liquid source 21 for supplying electrically conducting fluid 50 to probe 30.

Is an exemplary embodiment as thown in FIG. 1, elec-trosurgical probe 10 includes an elongated shaft 13 which may be flexible or rigid, with flexible shafts optionally including support cannulas or other structures (not shown). Probe 10 includes a connector 19 at its proximal end and an array 12 of electrode terminals \$8 disposed on the distal tip of shaft 13. A connecting cable 34 has a handle 22 with a connector 20 which can be removably connected to cons tor 19 of probe 10. The proximal portion of cable 34 has a connector 26 to couple probe 10 to power supply 28. The electrode terminals 58 are electrically isolated from each other and each of the terminals SS is connected to an active or passive counci network within power supply 28 by means of a pimulity of individually insulated conductors 42 (see PIG. 2C). Power supply 28 has a selection means 30 change the applied voltage level. Power supply 28 also Includes means for encryizing the electrodes 58 of probe 19 through the depression of a pedal 39 in a foot pedal 37 positioned close to the user. The foot pedal 37 may also include a second pedal (not shown) for remotely adjusting the energy level applied to electrodes SS. The specific design of a power supply which may be used with the electron gical probe of the present invention is described in parent application PCT US 94/05/168, the full disclosure of which has previously been incorporated herein by reference.

Referring to FRGS. 2A and 2B, the electrically isole clectrode terminals 58 are speced-sport over an electrode array surface 12. The electrode array surface \$2 and individual electrode terminals 58 will usually have dimensions within the ranges set forth above. In the preferred embodiment, the electrode array surface \$2 has a circular cross-sectional shape with a diameter D (FIG. 2B) in the range from 0.3 mm to 10 mm. Electrode array surface \$2 may also have so oval thape, having a length L in the range of 1 mm to 20 mm and a width W in the range from 0.3 m to 7 mm, as shows in FKJ. S. The individual electrode terminals 53 will proceede over the electrode array surface 82 by a distance (H) from 0 mm to 2 mm, preferably from 0 mm to 1 mm (see FIG. 5).

It should be noted that the electrode terminals may be flush with the electrode array surface \$2, or the termis may be recessed from the surface. For example, in deems-tological procedures, the electrode terminals 58 may be recessed by a distance from 0.01 mm to 1 mm, prefer 0.01 mm to 0.2 mm. In one embodiment of the investion, the electrode terminals are axially adjustable relative to the electrode array surface \$2 so that the surgeon can adjust the distance between the surface and the electrode term

The electrode terminals 58 are preferably composed of a and preferably about 0.05 to 0.5 mm during the ablation 65 refractory, electrically conductive metal or alloy, such as platinum, tiunium, tantaium, tungsten and the Ilia. As shown in FIG. 2B, the electrode terminals 58 are anchored in a support matrix 48 of subable insulating material (e.g., ceramic or glass material, such as ahmina, zirconia and the like) which could be formed at the time of manufacture in a flat, hemispherical or other shape according to the requirements of a particular procedure. The preferred support matrix material is alumina, available from Kyocera laderial Ceramics Corporation, Elkpove, Ill., because of shigh thermal conductivity, good electrically insulative properties, high flexural modulus, resistance to carbon tracking, biocompatibility, and high melting point.

As shown in FIG. 2A, the support matrix 48 is adhesively joined to a tubular support member 78 that extends most or all of the distance between matrix 48 and the proximal end of probe 10. Tubular member 78 preferably comprises an electrically insulating material, such as an epoxy, injection moldable plastic or silicone-based material. In a preferred construction technique, electrode terminals 58 extend through pre-formed openings in the support matrix 48 so that they protrade above electrode array surface \$2 by the desired distance H (FIG. 3). The electrodes may then be boaded to the distal surface \$2 of support matrix 48, typically by an incorposic scaling material \$0. Scaling massmai 80 is relected to provide effective electrical inc and good editerion to both the ceramic matrix 48 and th n or thankun electrode terminals. Scaling material 80 additionally should have a compatible thermal expansion coefficient and a melting point well below that of platinum or titanium and alumina or zirconia, typically being a glass or glass cemanic.

In the embodiment shown in PIGS. 2A and 2B, probe 10 includes a return electrode 56 for completing the current path between electrode terminals 58 and power supply 28. Return electrode terminals 58 and power supply 28. Return electrode 56 is preferably an annulus member post-tioned around the exterior of shaft 13 of probe 10. Return electrode 56 may fully or partially circumscribe wheler support member 78 to form an annulus gap 54 thereforeway, as discussed below. Gap 54 preferably has a width in the maps of 0.15 mm to 4 mm. Return electrode 56 extends from the proximal end of probe 10, where R is nainably connected to go power supply 28 via connectors 19, 28, to a point slightly proximal of electrode array surface 82, typically about 0.5 to 10 mm and more preferably about 1 to 10 mm.

Return electrode 56 is disposed within an electrically immistive jacket 18, which is typically formed as one or as more electrically insulative sheaths or coatings, such as polyterrafluoreethylese, polyteride, and the like. The prevision of the electrically insulative jacket 18 over return electrode 56 prevents direct electrical contact between return electrode 56 and any adjacent body structure or the surgeon. 30 Such direct electrical contact between a body structure (e.g., tendon) and an exposed common electrode member 56 could result in unwanted besting and secrecis of the structure at the point of contact causing necrosis.

Return electrode 56 is preferably formed from an electrically conductive material, anually metal, which is selected
from the group consisting of stainless start alloys, platform
or its alloys, titunium or its alloys, molybelenum or its alloys,
and alcind or its alloys. The return electrode 56 may be
composed of the same metal or alloy which forms the
electrode terminals 58 to minimize any potential for conosion or the generation of electrochemical potentials due to
the presence of dissimilar metals contained within an elecrically conductive fluid 56, such as isotonic saline
(discussed in greater detail below).

As shown in PIG. 2A, return electrode 56 is not directly connected to electrode terminals 51. To complete this cur-

rent path so that terminals SS are electrically connected to return electrode 56 via target tissue 52, electrically conducting Hquid 56 (e.g., isotosic saline) is caused to flow along liquid path 83. A liquid path 83 is formed by assular gap 56 between outer searce electrode 56 and tubular support member 78. An additional liquid path 83 may be formed between as inner lumes 57 within an inner tubular member 59. However, it is generally preferred to form the liquid path 83 sear the perimeter of the probe so that the electrically conducting liquid tends to flow radially inward towards the target site 88 (this preferred embodiment is illustrated in FIGS, 3-19). In the embodiment shown in FIGS, 2-5, the liquid flowing through inner humen 57 may tend to splash potentially causing damage to the surrounding tissue.

The electrically conducting liquid 50 flowing through fluid paths 13 provides a pathway for electrical current flow between target tissue 52 and return electrode 54, as Illustrated by the current flow lines 60 in FIG. 2A. When a voltage difference is applied between electrode array 12 and return electrode 54, high electric field intensities will be generated at the distal tips of terminals 58 with current flow from array 12 through the target tissue to the setum electrode, the high electric field intensities causing abiation of tissue 52 in 2000 58.

PIGS. 2C. 3 and 4 libustrate as alternative embodiment of electrosurgical probe 30 which has a return electrode 55 positioned within tubular member 78. Return electrode 55 is preferably a tubular member defining an inner tumen 57 for allowing electrically conducting liquid 50 (e.g., isotosic allowing to flow therethrough in electrical contact with ruturn electrode 55. In this embodiment, a voltage difference is applied between electrode terminals 38 and return electrode 55 resulting in electrical current flow through the electrically conducting liquid 50 as shown by current flux lines 60 (FEG. 3). As a result of the applied voltage difference and concombant high electric field intensities at the tips of electrode terminals 58, dissue 52 becomes ablated or transocted in zone 58.

FRG. 2C filintrates the preximal or connector end 70 of probe 10 in the embodiment of FIGS. 3 and 4. Connector 19 comprises a plurality of individual connector plus 74 positioned within a housing 72 at the proximal end 70 of probe 18. Electrode terminals 58 and the attached insulating conductors 43 extend proximally to connector plus 74 in connector housing 72. Return electrode 55 extends into housing 72, where it beads radially outward to exit probe 18. As shown in FIGS. 1 and 2C. a liquid supply tube 15 semovably couplet liquid source 21, (e.g., a bag of fluid elevated above the surgical site or having a pumping device), with return electrode 55. Preferably, an insulating jacket 14 covers the exposed portions of electrode 55. One of the connector pins 76 is electrically connected to return electrode 55 to couple electrode 55 to power supply 20 via cable 34. A manual control valve 17 may also be provided between the proximal end of return electrode 55 and supply tube 15 to allow the surgical team to regulate the 8ew of electrically conducting liquid 36.

FIG. 6 Electristes mother embodiment of probe 10 where the distal portion of shaft 13 is bent so that electrode terminals extend transversely to the shaft. Preferably, the distal portion of shaft 13 is perpendicular to the seat of the shaft so that electrode array surface 82 is generally parallel to the shaft soin, as shown in FIG. 6. In this embodiment, is return electrode 85 is mounted to the outer surface of shaft 13 and is covered with an electrically insulating jacket 18. The electrically conducting fluid 50 flows along flow path 83

through return electrode 35 and exits the distal end of electrode 55 at a point proximal of electrode surface 82. The fluid is directed exterior of shaft to electrode surface \$2 to create a return current path from electrode terminals 58, through target tissue \$2, to return electrode \$5, as shown by current flux lines 64.

PIG. 7 illustrates another embodiment of the inventi where electrosurgical system 11 further includes a limit supply instrument 64 for supplying electrically conducting fluid 54 between electrode terminals 58 and return electrode 55. Liquid supply instrument 64 comprises an inner tubular member or return electrode 55 surrounded by an electrically insulating jacket 18. Return electrode 55 defines an inner passage 83 for flow of fluid 50. As shown in FIG. 7, the dired portion of instrument 64 is preferably boost so that liquid 50 is discharged at an angle with respect to instrument 64. This allows the surgical team to position liquid supply instrument 64 adjacent electrode surface 82 with the pr mal portion of supply instrument 64 oriented at a similar angle to probe 18.

FIGS. 8 and 9 libratrate another embodiment of probe 16 where the return electrode is an outer tobular member 56 that circumscribes support member 78 and conductors 42. Inst lining jacket 18 surrounds tubular member 56 and is speced from member 54 by a phyrality of longitudinal ribs 96 to define an annular gap 54 therebetween (FIG. 9). Annular gap preferably has a width in the range of 0.15 mm to 4 mm. Ribs 96 can be formed on either the jacket 18 or member 86. The distal end of renera electrode 56 is a distance L, from electrode support surface \$2. Distance L₁ is preferably about 0.5 to 10 mm and more preferably about 1 to 10 mm. The length 1. of return electrode 56 will generally depend on the electrical conductivity of the intigant solution.

As shown in FIG. 8, electrically conducting liquid 50 flows through annular gap 54 (in electrical communication with the reason electrode) and is discharged through the distal end of gap 54. The liquid 50 is then directed around through the state of gap 54. The liquid 50 is then directed around through the state of th support member 78 to electrode terminals 58 to provide the current pathway between the electrode terminals and return electrode 56. Since return electrode 56 is proximally recessed with respect to electrode surface \$2, contact between the return electrode 56 and surrounding tissue is minimized. In addition, the distance L₂ between the active electrode terminals 68 and the return electrode 54 reduces the risk of current shorting therebetwees.

The present invention is not limited to an electrode acres disposed on a relatively planar surface at the distal tip of probe 10, as described above. Referring to FIGS. 12-14. as alternative probe 10 includes a pair of electrodes \$8a, \$8b mounted to the distal cod of shaft 13. Electrodes \$8a, \$8b are electrically connected to power supply as described above and preferably have tips 100s, 100b with a screwdriver or flattened shape. The screwdriver shape provides a greater amount of "edges" to electrodes 58a, 58b, to increase the electric field intensity and current density at the edges and thereby improve the carring ability as well as the ability to limit bleeding from the inclied tissue (i.e., hemostasis).

As shown in PIG. 12, corrent flows between electrode tips 100s and 100b as indicated by current flux lines 60 to heat the target tissue 52. The surpose then moves probe 10 transversely across tissue 52 to effect an incision 102 in tissue 52, as shown in FRG. 14.

Other modifications and variations can be made to dis invention as defined in the following claims. For examp that: 13 of probe 10 may have a variety of configurations

other than the generally linear shape shows in FIGS. 1-4. For example, that 13 may have a dirtal portion that is angled, in the range of 10° to 30° (FiG. 10) or 90° (FiGS. 11 and 6), to improve access to the operative site of the tisse 52 being ablated or cut (see FIG. 10). A shaft having a 90' bend angle may be particular useful for accessing gingiva located in the back portion of the patient's mouth and a thath having a 10° to 30° bend angle may be useful for accessing giagive sear or in the front of the perient's mouth.

in addition, it should be noted that the invention is not limited to an electrode array comprising a plurality of active electrodes. The investion could willize a plansity of return electrodes, e.g., in a bipolar array or the like. In addition, depending on other conditions, such as the peak-to-peak voltage, electrodo diameter, etc., a single active electrode may be sufficient to develop a vapor layer and induce the discharge of energy to ablate or out tissue, as described

By way of example, FIGS. 21 and 22 illustrate the design of a probe 10 according to the present invention comprising a single active electrode S8 having a tubular geometry. As described above, the return electrode may be an outer tubular member 56 that circumscribes insulated conductor 42 and adhesive boading material 79 which, in turn, adhe sively joins to active electrode support members 46s and 48b. Electrode support members 48s and 48b may be ceramic, glass ceramic or other electrically insulating rial which resists carbon or are tracking. A preferred elec-trode support member material is alumina. In the example embodiment, a solid rod of alumina forms as laner portion 48b of electrode support member 48 and a bollow tube of alumina forms an outer portion 48s of electrode support member 48. Tubular shaped active electrode 58 may be fabricated using shaped cylinder of this metal comprising an electrically conductive metal, such as platform, tantalu tuagsten, molybdeaum, columbium or alloys thereof. Activo electrode 58 is connected to connector 19 (see FiG. 2C) vis as invulated lead 100. As electrically invulsting jacket 18 surrounds tubular member 56 and may be spaced from member 56 by a phurality of longitudiani ribs 96 to define an annular gap 54 therebetween (FEG. 22). Annular gap 54 preferably has a width in the range of 0.15 to 4 mm. Ribs 96 can be formed on either jacket 18 or tubular member 54. The distal end of the return electrode 56 is a distance L, from electrode support surface \$2. Distance L₁ is preferably about 0.5 mm to 10 mm and more preferably about 1 to 10 mm. The length L_1 of return electrode \$6 will generally depend on the electrical conductivity of the intigant solution.

As shows in FIG. 21, electrically conducting Equid 50 flows through annular gap 54 (in electrical communication with seturn electrode 54) and is discharged through the distal end of gap 54. The Bould 50 is then directed around electrode support member 48s to electrode terminal 58 to provide the current pathway between electrode terminal 58 and return electrode S6. As described above, the active and setura electrodes are connected to voltage supply 28 vis cable 34 (see PEG. 1).

FRGS, 23 and 24 Eliustrate further embodin trostrigical probes according to the present invention. In FIG. 23, a probe 10 comprises a multiplicity of electrodes 50 which converge to a single electrode lead 42. As shows, a central electrode 105 extends to the proximal end of the probe shaft for connection to connector 19 (FIG. 2C). The remainder of the electrodes S8 extend through a portion of closs embodiments without departing from the subject 65 the probe shaft and are electrically coupled to central electrode 165 by, for example, a weld, solder joint or crimp connection 100, In PIG. 24, an electrosurgical probe 10

comprises a single electrode 58 connected to a single electrode lead 42. As described above, the active and return electrodes are connected to voltage supply 28 via cable 34 (see FRG. I).

Both of the single active electrode configurations depicted in FIGS. 21–24 may be used with the integral supply means and return electrodes described above in FIGS. 2–11, 30 and 31. Alternatively, these probe configurations may be operated in body cavities already containing an electrically conducting Equid 50, obvising the need for either an integral supply of said liquid or an electrically insulating sleeve to form a conduct for supply of the electrically conducting Equid 50. Instead, an electrically insulating covering would be applied to substantially all of the return electrode 56 (other than the proximal portion).

FIG. 15 illustrates the current flux lines associated with an electric field 120 applied between the active and return electrodes 56, 58 when a voltage is applied therebetween. As shown, the electric field intensity is substantially higher in the region 88 at the tip of the electrode 58 because the current flux lines are concentrated in these regions. This high electric field intensity leads to induced molecular breakdown of the target tissue through molecular dissociation. Preferably, the electric field intensity is sufficient to ionize the vaporised electrically conducting liquid 50 as this layer 124 between the distal tip 122 of the active electrode 58 and the target tissue 52, as shown in FIG. 16. The vapor layer 124 will usually have a thickness of about 0.02 to 2.0 mm.

As shown in FIG. 16, the electric field loaines the vapor layer due to the presence of an ionizable species (a.g., rodkim) within the vapor layer to create a plasma. This ionization, under optimal conditions, induces the discharge of highly energetic electrons and/or photons from the vapor layer. The photon and/or the energetic electrons cause disintegration of the tissue molecules adjacent to the vapor layer. FIG. 16 illustrates the insurance of bubbles 126 of non-condensible gaseous products resulting from the disjacent on of tissue at the target site.

The system and method of the present invention is also useful in dermatological procedures, i.e., surface tissue ablation on the patient's outer atim or epidernais. For example, the probe of the present invention can be used for the removal of tissue abnormalities, pignocatations, such as frecides, instoon, ago or liver spots, birth marks, malignant melanomas, and superficial leatigines in the epidermis, and other unwanted tissue, such as not fairy tissue, cutaneous anglodyspiesia, e.g., akin angloma, malignant tumor tissue, humbago (i.e., tissue bulges extending from the verteinne) or the like. In addition, the probe of the present invention may be used for removing surface layers of the epidermis to provide younger looking skin (tissue rejuveration) or for incling, dividing and resecting tissue during connectic sur-

FIG. 17 illustrates an exemplary embodiment, where an 33 electrosurgical probe 130 is utilized to remove the surface layers of the epidermis 140. Probe 130 includes a shaft 133 coupled to a proximal handle 134 for holding and controlling shaft 132. Similar to previous embodiments, probe 130 includes an active electrode array 136 at the distal tip of 60 shaft 132, an annular return electrode 138 extending through thaft 132 and proximally recessed from the active electrode array 136 and an annular immen 142 between return electrode 138 and an outer insulating sheath 144. Probe 130 trather includes a liquid supply conduit 146 annached to handle 134 and in finid communication with lumen 142 and a source of electrically conducting fluid (not shown) for

delivering the fluid past return electrode 138 to the target site on the epidermis 148. As discussed above, electrode may 136 is preferably flush with the distal end of shaft 133 or distally extended from the distal end by a small distance on the order of 0.005 inches) so to minimize the depth of ablation. Preferably, the distal end of shaft 132 is bevoted to improve access and control of probe 130 while treating the epidermal distance.

The voltage will preferably be sufficient to establish high reterric field intensities between the active electrode array 136 and the epidermal tissue 140 to thereby induce molecular breakdown or disintegration of several cell layers of the epidermal tissue. As described above, a sufficient voltage will be applied to develop a thin layer of vapor within the electrically conducting field and to lonize the vaporitude layer or region between the active electrode(s) and the target tissue. Energy in the form of photons and/or energetic electrons are discharged from the vapor layer to ablate the epidermal tissue, thereby minimizing accrosis of surrounding tissue and underlying cell layers, such as cell structures in the strutum hecklism and/or strutum granulosum.

FRCS. 18-20 illustrate an exemplary embodiment of another important application of the process invention. As discussed above, the probe of the present invention may be particularly useful for boring a channel through tissue by stalily translating the probe towards the tissue as the tissue is disintegrated by the mechanisms discussed above. In the exemplary embodiment, the probe of the present invention it used in a transmyocardial revascularization procedure to form channels from the myocardium. To the ventricular cavity to perfuse the myocardium. This procedure is an alternative to coronary artery bypass surgery for treating coronary artery disease. The channels allow cavity from the north to directly flow into the myocardium; rather than exiting the heart and then flowing back into the myocardium through the coronary arteriet.

As shown in FIG. 18, electrosurgical probe 30 is positioned into one of the ventricular cavities of the heart, in this case, the right ventricle 200. Electrosurgical probe 10 may be introduced into the right ventricle 200 in a variety of procedures that are well known to the art, such as a thoracotomy, sternotomy or minimally invasive procedures. In the representative embodiment, probe 10 is introduced into the vasculature of the patient through a percutaseous penetration and artially transitised via a guide catheter 202 through one of the major vessels to the right westricular cavity 204. A preferred embodiment incorporates a steerable guide catheter 202 which can be enternally controlled by the surgeon to direct the distal portion of the guide catheter 202 and probe 10 to the target site(s) in ventricular cavity 204.

Referring to FiG. 19, ventricle wall 206 comprises as epicardium 208, a myocardium 210 and an endocardium 212. In the representative embodiment, probe 10 will foun a channel 214 or artificial vessel from the ventricular cavity 206, through the endocardium 212 and into the myocardium 210 to thereby lacrease myocardial blood flow from the endocardium 212 to the myocardium 216. The location of channel 214 may be aelected based on familiar epicardial automic landmarks, such as the epicardial branches of the coverny arteries. Guide catheter 202 is positioned edjacest the inear endocardial wall and probe 10 is axially translated to that the active electrode 58 at its distal end is positioned proximate the heart tissue. In this embodiment, the probe includes a single, annular electrode 58 at its distal up for ablation of the heart tissue. However, it will be medily recognized that the probe may include as army of electrode terminals as described in detail above.

Electrically conducting liquid 50 is delivered through an annular himen 220 between an annular return electrode 222 and an insulating sheath 224 of the probe. Return electrode 222 is recessed from the distal end of active electrode 58. preferably about 0.025 to 0.050 inches. Alternatively, the return electrode may be positioned on the exterior surface (skin) of the petient, or it may be located nearby on a mose proximal position of the probe. Similar to the above embodiments, a high frequency vokage (e.g., 100 kHz) is applied between active electrode(s) 58 and return electrode at 222 to establish a current flow therebetween that ablates or disintegrates the heart tissue. The high frequency voltage will preferably be sufficient to vaporize a thin layer of the electrically conducting liquid and to induce the discharge of photon and/or electron energy from the vapor layer to 15 provide cold ablation of the heart tissue.

Ablation of the tissue may be facilitated by axially reciprocating and/or rotating the probe within guide eatheter 202 a distance of between about 0.05 to 0.20 inches. This axial reciprocation or rotation allows the electrically conducting liquid 50 to flow over the tissue surface beis canalized, thereby cooling this tissue and preventing significant thermal damage to the surrounding tissue cells.

FIG. 24 Electrates an alternative embodiment of the probe of FIG. 1. In this embodiment, the probe 264 includes a central lumen 262 having a proximal end attached to a suitable vacuum source (not shows) and an open distal end 266 for aspirating the target site. The active electrode is preferably a single annular electrode 268 surrounding the open distal end 266 of central lumen 262. Central lumen 262 is utilized to remove the ablation products (e.g., liquids and gases) generated at the target site and excess electrically conductive irrigant during the procedure.

in both of the above embodiments, the present invention provides localized abiation or disintegration of heart tissue to form a revascularization channel 214 of controlled diameter and depth. Usually, the diameter will be in the range of 0.5 mm to 3 mm. Professbly, the radio frequency voltage will be in the range of 400 to 1400 volts peak-to-peak to provide controlled rates of tissue abiation and hemostasis while minimizing the depth of necrosis of tissue surrounding the desired channel. This voltage will typically be applied continuously throughout the procedure until the desired leagth of the channel 214 is completely formed. Howe the heartheat may be monitored and the voltage applied is pulses that are suitably timed with the contractions (systole)

It should be noted that the above embodiment is merely representative and is not intended to limit the investion. For example, the electrostripical probe can be used to effect a myocardial revascularization channel from the exterior of the heart late the vestricular cavity. In this procedure, the probe will be introduced into the thoracie cavity and posttioned adjacent the epicardial layer of one of the ventricular walls via one of a variety of conventional managers. The above electrosurgical procedure will then be performed as the electrode is translated towards the heart until a channel is formed to the ventricular cavity.

The system and method of the present invention may also be useful to efficaciously ablate (i.e., disintegrate) cancer cells and tissue containing cancer cells, such as cancer on the surface of the epidermia, eye, colon, bladder, cervix, were and the like. The present invention's ability to completely disintegrate the target tissue can be advantageous in this 43 application because simply vaporizing cancerous tissue may lead to spreading of viable cancer cells (i.e., seeding) to

other portions of the patient's body or to the surgical team in close proximity to the target assue. In addition, the cancerous turne can be removed to a precise depth while minimizing secrosis of the underlying tissue.
What is claimed is:

1. A method for applying energy to a target site on a patient body structure comprising:

providing an electrode terminal and a return electrode electrically coupled to a high frequency voltage source; positioning the active electrode in close proximity to the target site in the presence of an electrically conducting terminal: and

applying a high frequency voltage between the electrode terminal and the return electrode, the high frequency voltage being sufficient to vaporize the fluid in a thin layer over at least a portion of the electrode terminal and to induce the discharge of energy to the target size

in connect with the vapor layer.

2. The method of claim 1 wherein the electrode terminal comprises an electrode array including a plurality of isolated

electrode terminals.

3. The method of claim 2 wherein the isolated electrode terminals each have a contact surface area in the paage of about 0.25 mm² to 50.0 mm².

4. The method of claim 2 wherein the isolated electrode terminals have circular contact surfaces with an area in the range from 0.01 mm2 to 1 mm2

5. The method of claim 2 wherein the electrode terminals are spaced from each other a distance of about 0.0005 to 2.0

4. The method of claim 2 wherein the electrode array is disposed over a distal tip of an electrosurgical probe.
7. The method of claim 2 wherein the electrode terminals

countries a material with a relatively low thermal conduc-

8. The method of claim 7 wherein the electrode materials comprises a material selected from the group consisting of titanium, mogsten, platform, aluminum and tantalum.

9. The method of claim 2 wherein the seturn electrode has distal end positioned proximal to the electrode army. 10. The method of claim 2 wherein the electrode height of

the most distal portion of any of the electrode terminals relative to the most proximal portion of said electrode terminals exposed to the electrically conducting fluid is in the mage from 0.0 to 2.0 mm.

11. The method of claim 2 wherein the electrode terminals are surrounded and supported by an insulating matrix at ar hear the distal tip of the probe to electrically lichite proximal portions of the electrode terminals from the electrically conductive fluid, the insulating matrix comprising as incregazic meterial.

12. The method of claim 11 whereis the isorganic re rial is selected from the group consisting essentially of ceramic, giass and glass/ocramic composition

13. The method of claim 1 wherein at least a portion of the energy induced is in the form of photons having a waveleagth in the ultraviolet spectrum.

14. The method of claim 1 wherein at least a portion of the

energy is in the form of energetic electron

15. The method of claim 14 wherein the energy of the sergesic electrons is sufficient to cause disassociation or disintegration of molecules of the body structure.

16. The method of claim 14 wherein the energy evolved

by the energetic electrons is greater than 3 eV.

17. The method of claim I wherein the high frequency voltage is at least 200 volts peak to peak.

18. The method of claim I wherein the voltage is in the

range from 500 to 1400 volts peak to peak.

19. The method of claim 1 wherein the electrode termin is positioned between 0.02 to 5 mm from the target site.

28. The method of claim I wherein the vapor byer has a

thickness of about 0.02 to 2.0 mm.

21. The method of claim I wherein the distance between S the most proximal portion of the electrode terminal and the most distal portion of the secura electrode is in the mage from 0.5 to 10 mm

22. The method of claim I wherein the electrode terminal and the return electrode are of comparable size and comprise 10 a bipolar array of isolated electrode terminals which both come in close proximity or in contact with the body strate-

23. The method of claim I wherein the liquid phase of the electrically conducting fluid has a conductivity greater than 15 2 mS/cm

24. The method of claim I wherein the liquid phase of the electrically conductive fluid comprises isotonic saline.

25. The method of claim I wherein the electrode height of the most distal parties of the electrode terminal relative to 20 the most proximal portion of the electrode terminal exposed to the electrically conducting fluid is in the range from 0.0 to 20 mm.

26. A method for applying energy to a target site on a patient body structure comprising:

providing an active electrode and a return electrode electrically coupled to a high frequency voltage source;

positioning the electrode terminal in close proximity to the target site is the presence of an electrically conducting fluid; and

applying a high frequency voltage between the electrode terminal and the return electrode, the high frequen voltage being in the range from 500 to 1400 volts peak

27. The method of claim 24 wherein the high frequency voltage is in the range from 700 to 900 wolts peak to peak. 22. A method for applying energy to a target site on a patient body structure comprising:

providing an electrode terminal and a setura electrode electrically coupled to a high frequency voltage source;

positioning the electrode terminal in close proximity to the target site in the presence of an electrically conducting field; and

applying a high frequency voltage between the electrode 45 terminal and the return electrode, the high frequency voltage being sufficient to impart sufficient energy into the target alle to ablate the body structure without causing substantial tissue necrosis below the surface of the body structure underlying the ablated body struc-

29. The method of claim 28 wherein the applying stop committee

vaporizing the electrically conducting fluid in a this layer over at least a portion of the electrode terminal; and inducing the discharge of photons to the target site in

contact with the vapor layer. 30. The method of claim 28 wherein the applying step

vaporizing the electrically conducting fluid in a thin layer over at least a portion of the active electrode surface;

inducing the discharge of exergetic electrons to the target site in contact with the vapor layer.

31. The method of claim 28 wherein the depth of accrosis is 0 to 400 micross.

32. A method for applying energy to a target size on a patient body structure comprising:

providing an active electrode electrically coupled to a high frequency voltage source;

positioning the electrode terminal in close proximity to the target site in the presence of an electrically conducting fluid; and

generating a voltage gradient between the electrode tesminal and tissue at the target site, the voltage gradient being sufficient to create an electric field that cause the breakdows of tissue through molecular dissociation or disintegration.

33. The method of claim 32 wherein the generating stop compdees:

providing a return electrode electrically coupled to a high frequency voltage source;

applying a high frequency voltage between the electrode al and the return electrode; and

vaporizing the electrically conducting fiuld in a thin layer over at least a portion of the electrode terminal.

34. The method of claim 33 further comprising develo ing a film layer of vapor between the active electrode and d body structure at the target site.

35. The method of claim 35 further comprising cooling the tissue with the electrically conducting fluid to reduce the temperature rise of those portions of the body structure adjacent the target size.

36. The method of claim 35 wherein the cooling step includes translating the distal surface of the electrode terminal over the target site to allow the electrically conducting fluid to contact the tissue after the tissue has been subjecte to the electric Sold.

37. The method of claims 1 and 28 whereis the electrode terminal is surrounded and supported by an insulating matrix at or near the distal tip of the probe to electrically isolate the proximal portion of the electrode terminal from the electri-cally conductive fuld, the insulating matrix comprising an narale med

38. The method of claim 37 wherein the inorganic : rial is selected from the group consisting essentially of ceramic, glass and glass/ceramic compositions.

39. The method of claim 37 wherein the distal surface of the electrode terminal is recessed below the surface of the involuting metrix by a distance from 0.01 mm to 1.0 mm.

40. The method of claim 37 wherein the distal surface of the electrode terminal is flush with the surface of the senisting matrix

41. The method of claims 23 and 32 wherein the electrode terminal comprises an electrode army including a plurality of isolated electrode terminals.

42. The method of claim 41 wherein the generating step

providing a return electrode electrically coupled to a

higher frequency voltage source; applying a high frequency voltage between the return electrode and the array of electrode terminals; and

vaporizing the electrically conducting field in a thin layer over one or more of the electrode terminals of the array.

43. The method of claim 42 further comprising developng a film layer of vapor between one or more of the electrode terminals and the target site.

44. The method of claim 43 further comprising cooling the fissue with the electrically conducting fluid to reduce the emperature rise of those portions of the body structure ceat the target site.

45. The method of claims 1 and 33 wherein the density of the vapor layer is less than about 1000 atomatons.

46. The method of claims I and 30 wherein the electrode terminal is configured to promote bubble aucleation causing the formation of the vapor layer.

47. The method of claims 1 and 28 wherein the electrode

terminal has a contact surface area in the range of about 0.25 5 mm² to 50 mm².

48. The method of claims 26 and 28 whereis the high frequency voltage is at least 200 volta peak to peak.

49. The method of claims 26 and 28 wherein the high

yolks peak to peak.

50. The method of claims 26 and 28 wherein the electrode

terminal is positioned between 0.02 to 2.0 mm from the target site.

53. The method of claims 26 and 28 wherein the electrode 15 terminal and the return electrodes comprise a bipolar array of isolated electrode terminals.

52. The method of claims 1 and 28 further comprising cooling the therate with the electrically conducting fluid to

teduce the temperature rise of those portions of the body structure adjacent the target sits.

53. The method of dains 52 wherein the cooling step includes translating the distal surface of the active electrode over the target site to allow the electrically conducting fluid to contact the tissue after the tissue has been subjected to the electric Beld.

54. The method of claims 1 and 28 further comprising frequency voltage is in the range from about 500 to 1400 to evacuating fluid generated at the target site with a suction himen having a distal end adjacent the electrode terminal.

55. The method of claims 1 and 28 wherein the target site is a tumor within or on the patient's body.

56. The method of claims 26 and 28 wherein the electrode terminal comprises an electrode array including a plurality of isolated electrode terminals.

PATENT NO. : 5,697,882

DATED

December 16, 1997

INVENTOR(S): Philip E. Eggers, et. al.

It is cartified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

IN THE CLAIMS:

23. A method for applying energy to a target site on a patient body structure

comprising:

providing an electrode terminal and a return electrode electrically coupled to a

high frequency voltage source;

positioning the [active] electrode terminal in close proximity to the target site in

the presence of an electrically conducting [terminal] fluid; and

applying a high frequency voltage between the electrode terminal and the return electrode, the high frequency voltage being sufficient to vaporize the fluid in a thin layer over at least a portion of the electrode terminal and to induce the discharge of energy to the target size in contact with the vapor layer.

> Signed and Sealed this Seventh Day of April, 1998

Amest:

RADICE LEMINAR

Anesing Officer

5,697,882 PATENT NO. :

Page 1 of 2

DATED

: December 16, 1997

INVENTOR(S): Philip E. Eggers et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

IN THE CLAIMS:

- 37. The method of claims 23 or 48 wherein the electrode terminal is surrounded and supported by an insulating matrix at or near the distal tip of the probe to electrically isolate the proximal portion of the electrode terminal from the electrically conductive fluid, the insulating matrix comprising an inorganic material.
- 45. The method of claims 23 or 55 wherein the density of the vapor layer is less than about 10th MOUNT COM.
- 46. The method of claims 23 or 50 wherein the electrode terminal is configured to promote bubble nucleation causing the formation of the vapor layer.
- 47. The method of claims 23 or 48 wherein the electrode terminal has a contact surface area in the range of about 0.25 mm² to 50 mm².
- 48. The method of claims 48 or 52 wherein the high frequency voltage is at least 200 volts peak to peak.
- 49. The method of claims 48 or 52 wherein the high frequency voltage is in the range from about 500 to 1400 volts peak to peak.
- 50. The method of claims 48 or 52 wherein the electrode terminal is positioned between 0.02 to 2.0 mm from the target site.
- 51. The method of claims 48 or 52 wherein the electrode terminal and the return electrodes comprise a bipolar array of isolated electrode terminals.

PATENT NO. : 5,697,882

Page 2 of 2

DATED

: December 16, 1997

INVENTOR(S): Philip E. Eggers et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

- 52. The method of claims 23 or 48 further comprising cooling the tissue with the electrically conducting fluid to reduce the temperature rise of those portions of the body structure adjacent the target site.
- 54. The method of claims 23 or 48 further comprising evacuating fluid generated at the target site with a suction lumen having a distal end adjacent the electrode terminal.
- 55. The method of claims 23 or 48 wherein the target site is a numor within or on the patient's body.
- 56. The method of claims 48 or 52 wherein the electrode terminal comprises an electrode array including a plurality of isolated electrode terminals.

Signed and Sealed this Second Day of May, 2000

Attesting Offices

PATENT

: 5,697,882

DATED

: December 16, 1997

INVENTOR(S): Philip E. Eggers et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 24, lines 6-18, claim 1, should read as follows:

1. A method for applying energy to a target site on a patient body structure comprising:

providing an electrode terminal and a return electrode electrically coupled to a high frequency voltage source:

positioning the electrode terminal in close proximity to the target site in the presence of an electrically conducting fluid; and

applying a high frequency voltage between the electrode terminal and the return. electrode, the high frequency voltage being sufficient to vaporize the fluid in a thin layer over it least a portion of the electrode terminal and to induce the discharge of energy to the target site in contact with the vapor layer.

This certificate supersedes Certificate of Correction issued April 7, 1998.

Signed and Sealed Utis

Twenty-fifth Day of Angust, 1998

BRUCE LEMMAN

Anexing Officer



5697832A

United States Patent [19]

Eggers et al.

[11] Patent Number:

5,697,882

[45] Date of Patent:

Dec. 16, 1997

[54]	SYSTEM AND METHOL ELECTROSURGICAL C	
	ABLATION	•

[75] Inventors: Philip E. Eggers, Dublin, Ohio; Hira

V. Thapliyal, Los Altos, Calif.

[73] Assignee: Arthrocare Corporation. Sunnyvale.

Calif.

[21] Appl. No.: 561,958

[22] Filed: Nov. 22, 1995

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 485,219, Jun. 7, 1995, which is a continuation-in-part of Ser. No. 59,681, May 10, 1993, abandoned, which is a continuation-in-part of Ser. No. 958,977, Oct. 9, 1992, Par. No. 5,366,443, which is a continuation-in-part of Ser. No. 817,575, Jan. 7, 1992, abandoned.

[51]	Int. CL ⁶	A61B 1/0	9
[52]	Ü.S. CL	604/114; 604/2	2
[58]	Field of Search	504/114, 22, 28	i,

604/49, 113, 41; 606/27-32, 35, 38, 41

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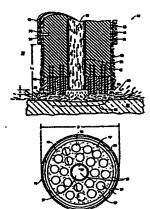
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Primary Examiner—Manuel Mendez
Assormes, Agent, or Firm—Townsend and Townsend and
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[57] ABSTRACT

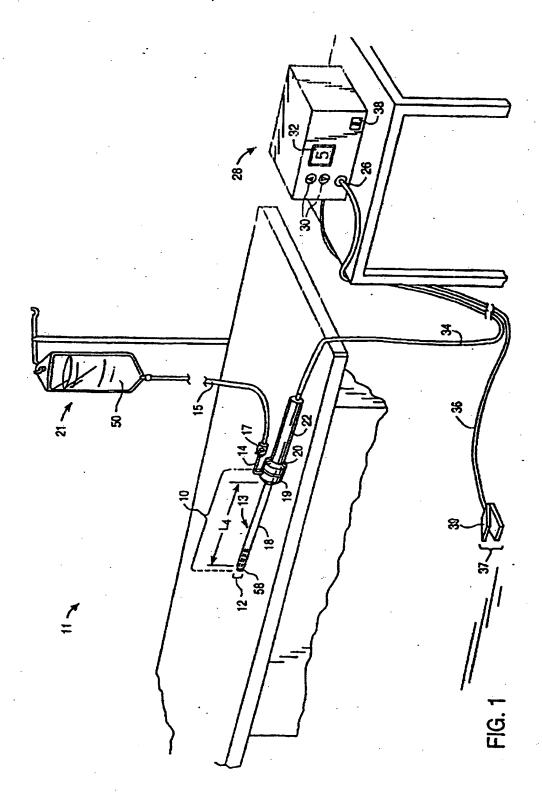
An electrosurgical probe (10) comprises a shaft (13) having an electrode array (58) at its distal end and a connector (19) at its proximal end for coupling the electrode array to a high frequency power supply (28). The shaft includes a return electrode (56) recessed from its distal end and enclosed within an insulating jacket (18). The return electrode defines an inner passage (83) electrically connected to both the return electrode and the electrode array for passage of an electrically conducting liquid (50). By applying high frequency voltage to the electrode array and the return electrode, the electrically conducting liquid generates a current flow path between the return electrode and the electrode array so that target tissue may be cut or ablated. The probe is particularly useful in dry environments, such as the mouth or abdominal cavity, because the electrically conducting liquid provides the necessary return current path between the active and return electrodes.

56 Claims, 17 Drawing Sheets



5,697,882 Page 2

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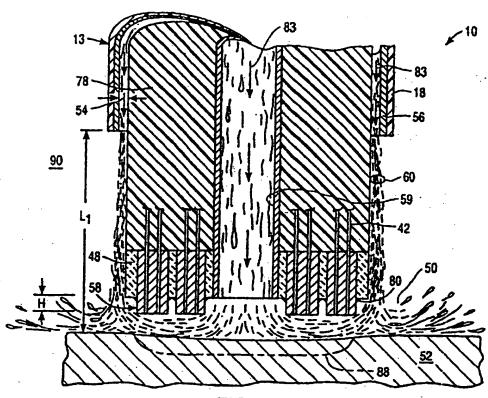
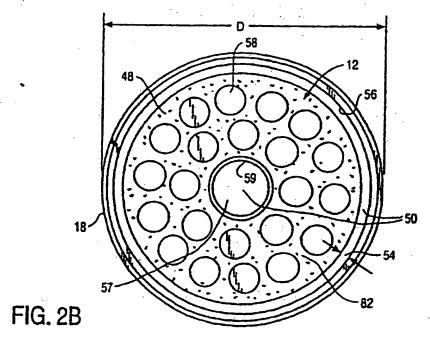


FIG. 2A



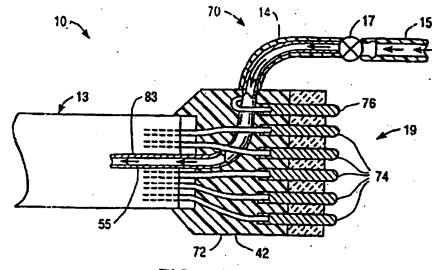
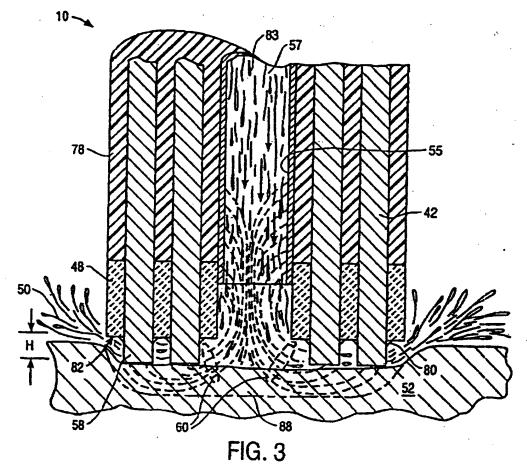


FIG. 2C



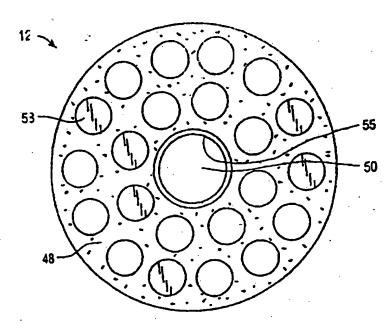


FIG. 4

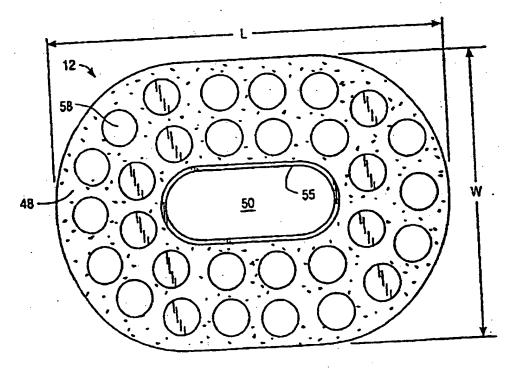
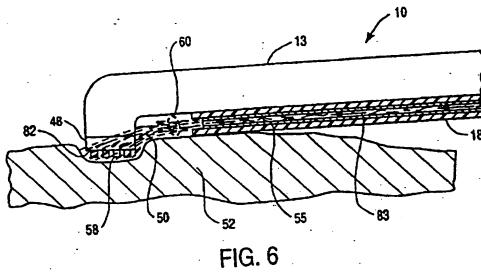
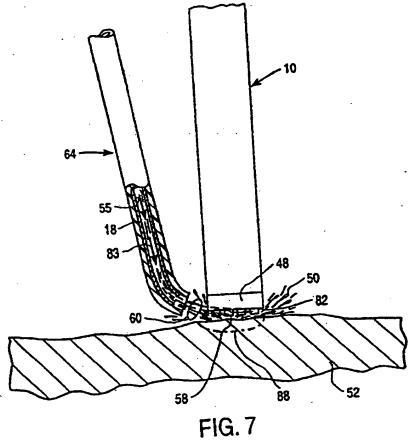


FIG. 5





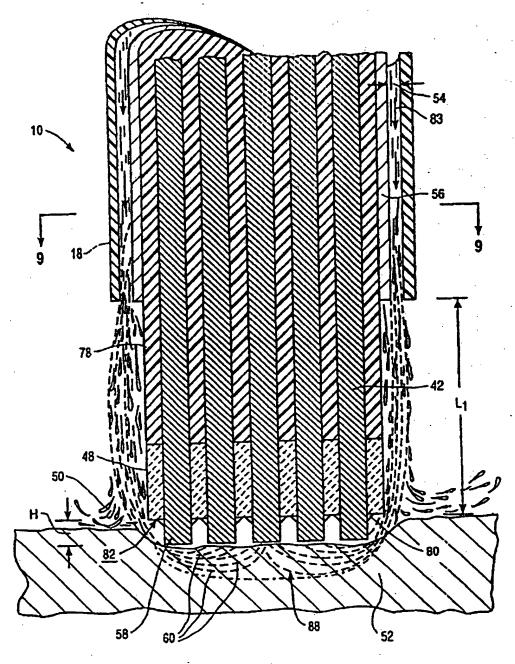
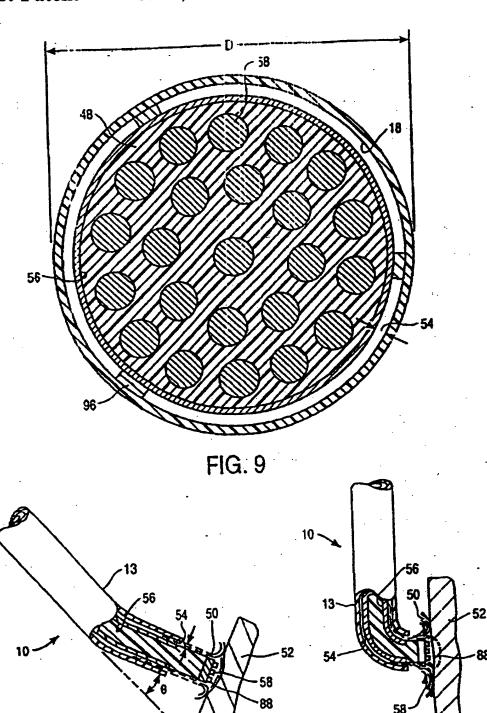


FIG. 8



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FIG. 11

FIG. 10

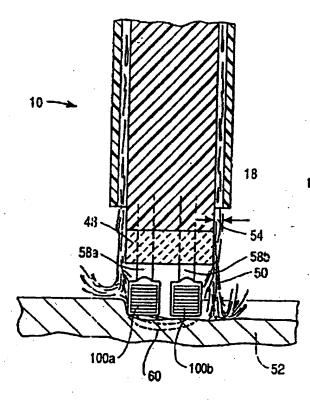
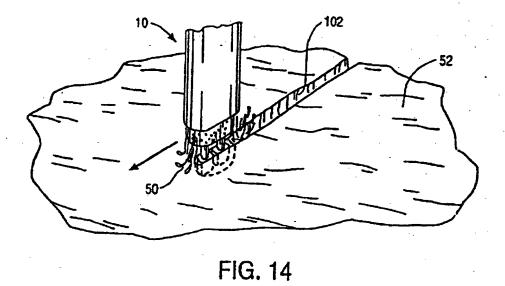


FIG. 13

FIG. 12



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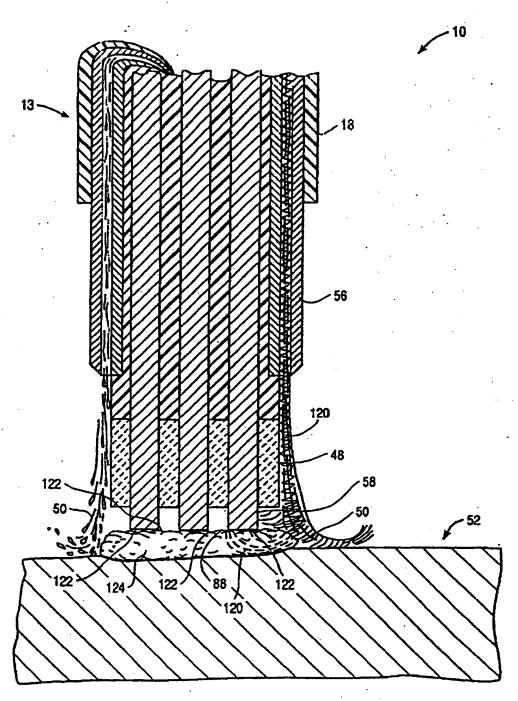
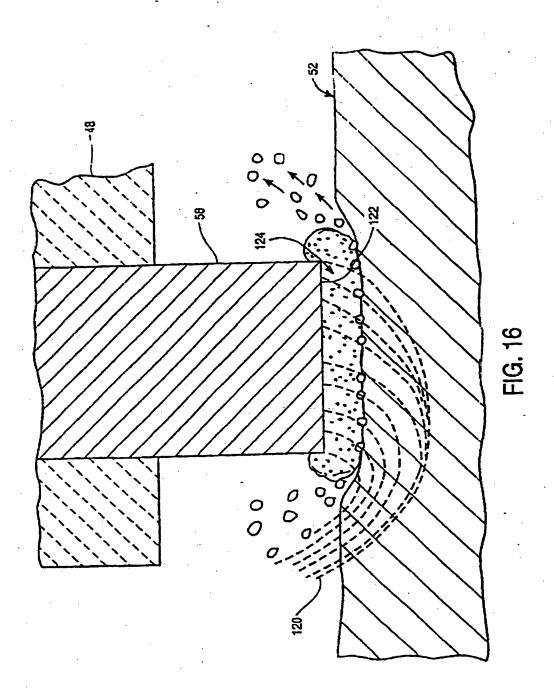
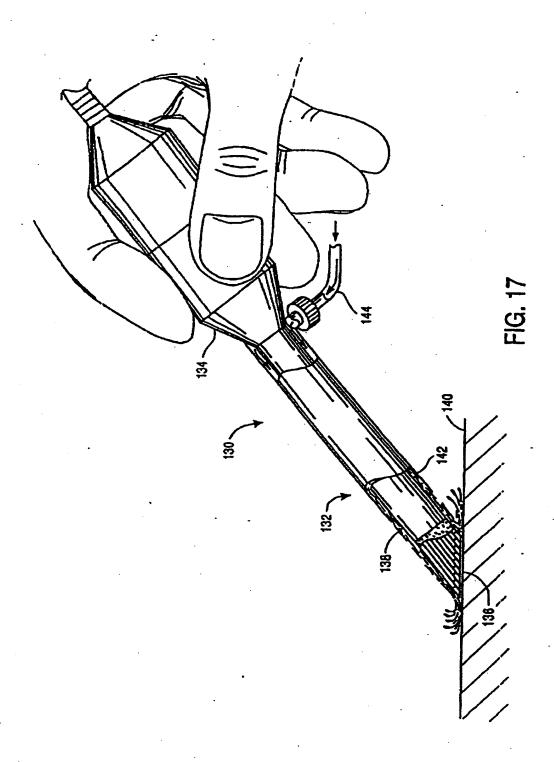


FIG. 15





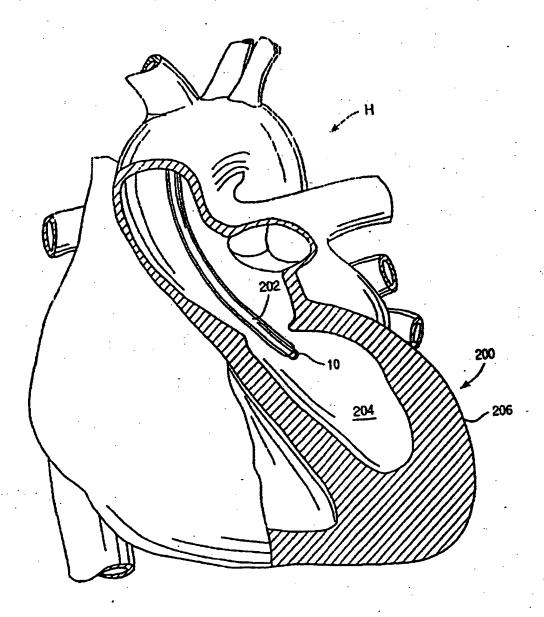


FIG. 18

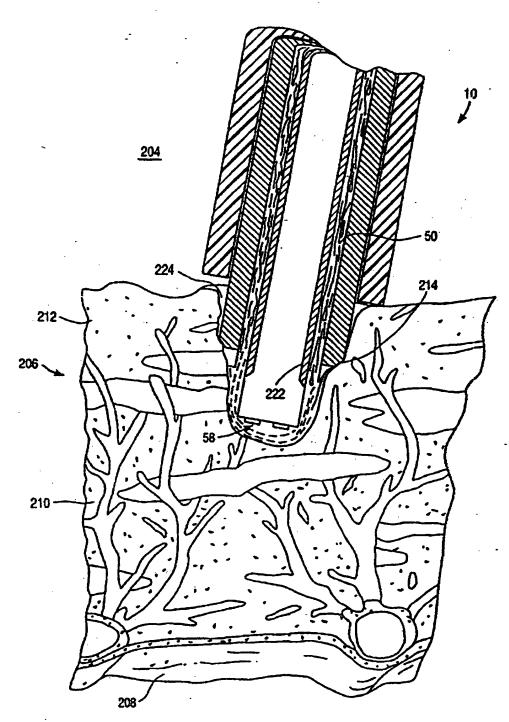


FIG. 19

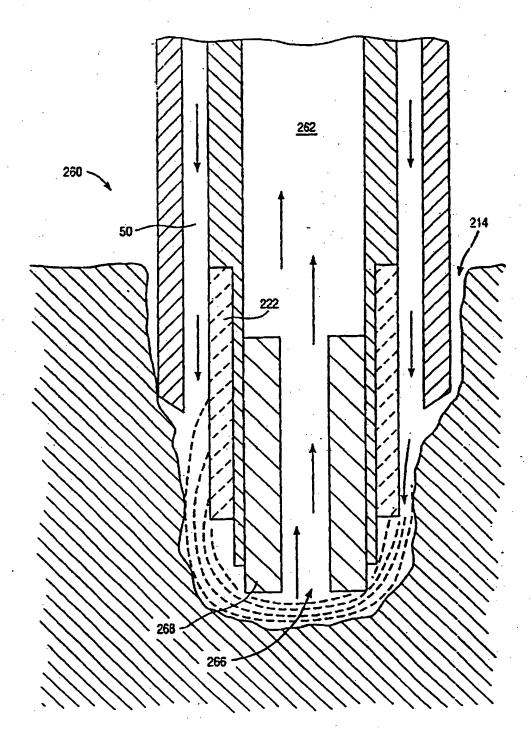


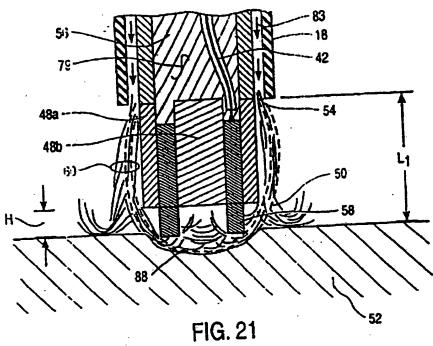
FIG. 20

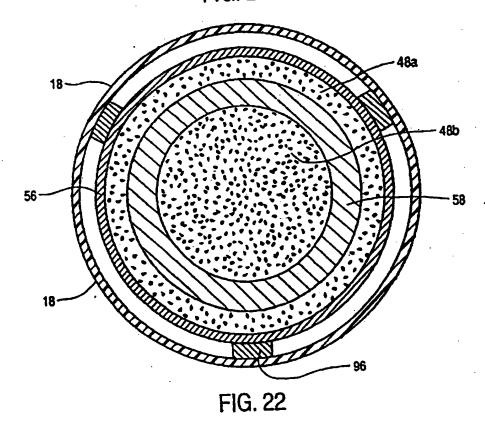




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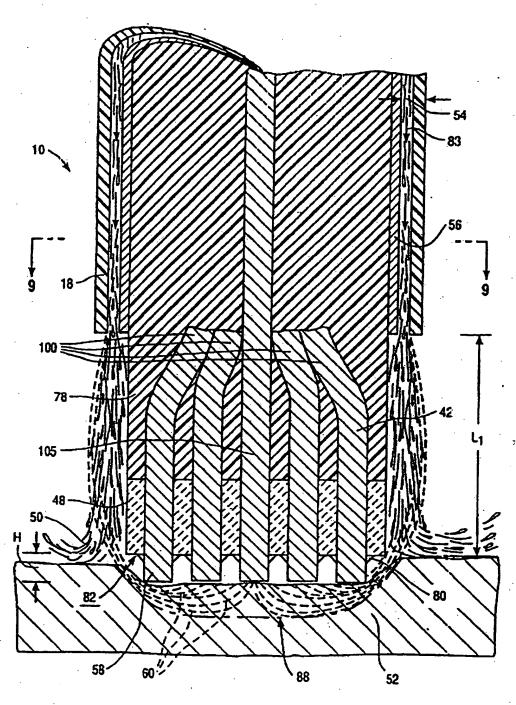


FIG. 23

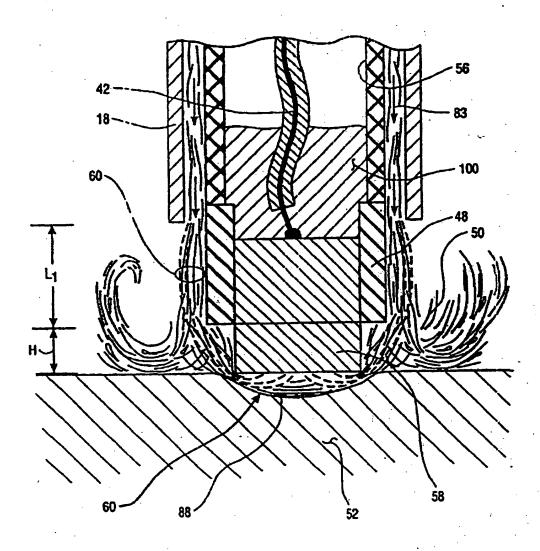


FIG. 24

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SYSTEM AND METHOD FOR ELECTROSURGICAL CUTTING AND ABLATION

BACKGROUND OF THE INVENTION

The present invention is a continuation-in-part of application Scr. No. 08/485,219, filed on Jun. 7, 1995 and still pending. which was a continuation-in-part of PCT International Application. U.S. National Phase Serial No. PCT/US94/05168, filed on May 10, 1994, which was a continuation-in-part of application Scr. No. 08/059,681, filed on May 10, 1993 and now abandoned, which was a continuation-in-part of application Scr. No. 07/958,977, filed on Oct. 9, 1992 now U.S. Pat. No. 5,366,443, which was a continuation-in-part of application Scr. No. 07/817, 1575, filed on Jan. 7, 1992 now abandoned, the full disclosures of which are incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates generally to the field of electrosurgery and, more particularly, to surgical devices and methods which employ high frequency voltage to cut and ablate tissue.

The field of electrosurgery includes a number of loosely related surgical techniques which have in common the application of electrical energy to modify the structure or integrity of patient tissue. Electrosurgical procedures usually operate through the application of very high frequency currents to cut or ablate tissue structures, where the operation can be monopolar or bipolar. Monopolar techniques rely on external grounding of the patient, where the surgical device defines only a single electrode pole. Bipolar devices comprise both electrodes for the application of current between their surfaces.

Electrosurgical procedures and techniques are particularly advantageous since they generally reduce patient bleeding and trauma associated with cutting operations. Current electrosurgical device and procedures, however, suffer from a number of disadvantages. For example, monopolar devices generally direct electric current along a defined path from the exposed or active electrode through the patient's body to the return electrode, which is externally attached to a suitable location on the patient. This creates the potential danger that the electric current will flow through undefined paths in 45 the patient's body, thereby increasing the risk of unwanted electrical stimulation to portions of the patient's body. In addition, since the defined path through the patient's body has a relatively high impedance (because of the large distance or resistivity of the patient's body), large voltage 50 differences must typically be applied between the return and active electrodes in order to generate a current suitable for ablation or cutting of the target tissue. This current, however, may inadvertently flow along body paths having less impedance than the defined electrical path, which will substan- 55 tially increase the current flowing through these paths, possibly causing damage to or destroying tissue along and surrounding this pathway.

Bipolar electrosurgical devices have an inherent advantage over monopolar devices because the return current path 60 does not flow through the patient. In bipolar electrosurgical devices, both the active and return electrode are typically exposed so that they may both contact tissue, thereby providing a return current path from the active to the return electrode through the tissue. One drawback with this 65 configuration, however, is that the return electrode may cause tissue desiccation or destruction at its contact point

with the patient's tissue. In addition, the active and return electrodes are typically positioned close together to ensure that the return current flows directly from the active to the return electrode. The close proximity of these electrodes generates the danger that the current will short across the electrodes, possibly impairing the electrical control system and/or damaging or destroying surrounding tissue.

The use of electrosurgical procedures (both monopolar and bipolar) in electrically conductive environments can be further problematic. For example, many arthroscopic procedures require flushing of the region to be treated with isotonic saline (also referred to as normal saline), both to maintain an isotonic environment and to keep the field of viewing clear. The presence of saline, which is a highly conductive electrolyte, can also cause shorting of the electrosurgical electrode in both monopolar and bipolar modes. Such shorting causes unnecessary heating in the treatment environment and can further cause non-specific tissue destruction.

Many surgical procedures, such as oral, laparoscopic and open surgical procedures, are not performed with the target tissue submerged under an irrigant. In laparoscopic procedures, such as the resection of the gall bladder from the liver, for example, the abdominal cavity is pressurized with carbon dioxide (pneumoperitoneum) to provide working space for the instruments and to improve the surgeon's visibility of the surgical site. Other procedures, such as the ablation of muscle or gingiva tissue in the mouth, the ablation and necrosis of diseased tissue, or the ablation of epidermal tissue, are also typically performed in a "dry" environment or field (i.e., not submerged under an electrically conducting irrigant).

Present electrosurgical techniques used for tissue ablation also suffer from an inability to control the depth of necrosis in the tissue being treated. Most electrosurgical devices rely on creation of an electric are between the treating electrode and the tissue being cut or ablated to cause the desired localized heating. Such arcs, however, often create very high temperatures causing a depth of necrosis greater than 500 µm, frequently greater than 800 µm, and sometimes as great as 1700 µm. The inability to control such depth of necrosis is a significant disadvantage in using electrosurgical techniques for tissue ablation, particularly in arthroscopic procedures for ablating and/or restaping fibrocartilage, articular cartilage, meniscal tissue, and the like.

In an effort to overcome at least some of these limitations of electrosurgery, laser apparatus have been developed for use in arthroscopic and other procedures. Lasers do not suffer from electrical shorting in conductive environments. and certain types of lasers allow for very controlled cutting with limited depth of necrosis. Despite these advantages, laser devices suffer from their own set of deficiencies. In the first place, laser equipment can be very expensive because of the costs associated with the laser light sources. Moreover, those lasers which permit acceptable depths of necrosis (such as eximer lasers, erbinm:YAG lasers, and the like) provide a very low volumetric ablation rate, which is a particular disadvantage in cutting and ablation of fibrocartilage, articular cartilage, and meniscal tissue. The holmium:YAG and Nd:YAG lasers provide much higher volumetric abiation rates, but are much less able to control depth of necrosis than are the slower laser devices. The CO2 lasers provide high rate of ablation and low depth of tissue necrosis, but cannot operate in a liquid-filled cavity.

For these and other reasons, improved systems and methods are desired for the electrosurgical ablation and cutting of

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tissue. These systems and methods should be capable of selectively cutting and ablating tissue and other body structures in electrically conductive environments, such as regions filled with blood or irrigated with electrically conductive solutions, such as isotonic saline, and in relatively dry environments, such as those encountered in oral, dermatological, laparoscopic, thoracosopic and open surgical procedures. Such apparatus and methods should be able to perform cutting and ablation of tissues, while limiting the depth of necrosis and limiting the damage to tissue adjacent 10 to the treatment site.

DESCRIPTION OF THE BACKGROUND ART

Devices incorporating radio frequency electrodes for use in electrosurgical and electrocantery techniques are described in Rand et al. (1985) J. Arthro. Surg. 1:242-246 and U.S. Pat. Nos. 5.281.216; 4.943.290; 4.936.301; 4.593, 691; 4.228.800; and 4.202.337. U.S. Pat. Nos. 4.943.290 and 4.036.301 describe methods for injecting non-conducting liquid over the tip of a monopolar electrosurgical electrode to electrically isolate the electrode, while energized, from a surrounding electrically conducting irrigant. U.S. Pat. Nos. 5.195.959 and 4.674.499 describe monopolar and bipolar electrosurgical devices, respectively, that include a conduit for irrigating the surgical site.

U.S. Pat. Nos. 5,217,455, 5,423,803, 5,102,410, 5,282, 797. 5.290.273, 5,304.170, 5,312,395, 5,336.217 describe laser treatment methods for removing abnormal skin ceils, such as pigmentations, lesions, soft tissue and the like. U.S. Pat. Nos. 5,445,634 and 5,370,642 describe methods for using laser energy to divide, incise or resect tissue during cosmetic surgery. U.S. Pat. No. 5,261,410 is directed to a method and apparatus for detecting and removing malignant tumor tissue. U.S. Pat. Nos. 5,380,316, 4,658,817, 5,389, 096, PCT application No. WO 94/14383 and European Patent Application No. 0 515 867 describe methods and apparatus for percutaneous myocardial revascularization. These methods and apparatus involve directing laser energy against the heart tissue to form transverse channels through the myocardium to increase blood flow from the ventricular cavity to the myocardium.

SUMMARY OF THE INVENTION

The present invention provides a system and method for 45 selectively applying electrical energy to structures within or on the surface of a patient's body. The system and method allow the surgical team to perform electrosurgical interventions, such as ablation and cutting of body structures, while limiting the depth of necrosis and limiting 50 damage to tissue adjacent the treatment site. The system and method of the present invention are useful for surgical procedures in relatively dry environments, such as treating and shaping gingiva, for tissue dissection, e.g. separation of gall bladder from the liver, ablation and necrosis of diseased 55 tissue, such as fibroid tumors, and dermatological procedures involving surface tissue ablation on the epidermis, such as sear or tattoo removal, tissue rejuvenation and the like. The present invention may also be useful in electrically conducting environments, such as arthroscopic or cystoscopic surgical procedures. In addition, the present invention is useful for canalizing or boring channels or holes through tissue, such as the ventricular wall of the heart during transmyocardial revascularization procedures

The method of the present invention comprises position-65 ing an electrosurgical probe adjacent the target tissue so that at least one active electrode is brought into close proximity

to the target site. A return electrode is positioned within an electrically conducting liquid, such as isotonic saline, to generate a current flow path between the target site and the return electrode. High frequency voltage is then applied between the active and return electrode through the current flow path created by the electrically conducting liquid in either a bipolar or monopolar manner. The probe may then be translated, recurrented or otherwise manipulated to cut the tissue or effect the desired depth of ablation.

The current flow path may be generated by submerging the tissue site in an electrical conducting fluid (e.g., arthroscopic surgery and the like) or by directing an electrically conducting liquid along a fluid path past the return electrode and to the target site to generate the current flow path between the target site and the return electrode. This latter method is particularly effective in a dry environment (i.e., the tissue is not submerged in fluid), such as open, endoscopic or oral surgery, because the electrically conducting liquid provides a suitable current flow path from the target site to the return electrode. The active electrode is preferably disposed at the distal end of the probe and the return electrode is spaced from the active electrode and enclosed within an insulating sheath. This minimizes exposure of the return electrode to surrounding tissue and minimizes possible shorting of the current between the active and return electrodes. In oral procedures, the probe may be introduced directly into the cavity of the open mouth so that the active electrode is positioned against gingival or mncosal tissue. In endoscopic procedures, the probe will typically be passed through a conventional trocar cannula while viewing of the operative site is provided through the use of a laparoscope disposed in a separate cannula.

In a specific aspect of the invention, the high frequency voltage applied between the active and return electrodes generates high voltage gradients in the vicinity of the probe tip. These high voltage gradients are sufficient to create an electric field at the distal boundary of the active electrode(s) that is sufficiently high to break down the tissue through molecular dissociation or disintegration. The high frequency voltage imparts energy to the target site to ablate a thin layer of tissue without causing substantial tissue necrosis beyond the boundary of the thin layer of tissue ablated. This ablative process can be precisely controlled to effect the volumetric removal of tissue as thin as a few layers of cells with minimal heating of or damage to surrounding or underlying tissue structures.

Applicants believe that this precisely controlled ablation is at least partly caused by the high electric field generated around the tip of the active electrode(s) within the electrically conductive liquid. The electric field vaporizes the electrically conductive liquid into a thin layer over at least a portion of the active electrode surface and then ionizes the vapor layer due to the presence of an ionizable species within the liquid. This ionization and the presence of high electric fields in a low density vaporized layer induces the discharge of highly energetic electrons and photons in the form of ultraviolet energy from the vapor layer. The ultraviolet energy and/or energetic electrons cause disintegration of the tissue molecules adjacent to the vapor layer. This energy discharge can be precisely controlled to effect the volumetric removal of tissue thicknesses ranging from millimeters to a few layers of cells without heating or otherwise damaging surrounding or underlying cell structures.

The active electrode(s) will be spaced away from the starget tissue by a suitable distance during the ablation process. This spacing allows for the continual resupply of electrically conducting liquid at the interface between the

active electrode(s) and the target tissue surface. This continual resupply of the electrically conducting liquid helps to ensure that the thin vapor layer or region will remain over at least a portion of the active electrode(s) between the active electrode(s) and the tissue surface. Preferably, the active 5 electrode(s) will be translated and/or rotated transversely relative to the tissue, i.e., in a light brushing motion, to maintain the supply of electrically conducting fluid in the region between the active electrode(s) and the tissue. This dynamic movement of the active electrode(s) over the tissue 10 site also allows the electrically conducting liquid to cool the tissue surrounding recently ablated areas to minimize damage to this surrounding tissue.

The apparatus according to the present invention comprises an electrosurgical probe having a shaft with a proximal end, a distal end, and at least one active electrode at or near the distal end. A connector is provided at or near the proximal end of the shaft for electrically coupling the active electrode to a high frequency voltage source. A return electrode coupled to the voltage source is spaced a sufficient 20 distance from the active electrode to substantially avoid or minimize current shorting therebetween and, in dry environments, to shield the return electrode from tissue at the target site of ablation or from the surgeon. In irrigant flooded environments, such as arthroscopic surgery, the area 25 of the return electrode is sufficiently large to result in low current densities that effectively preclude damage to nearby tissue. The return electrode may be provided integral with the shaft of the probe or it may be separate from the shaft (e.g., on a liquid supply instrument). In both cases, the return 30 electrode defines an inner, annular surface of the pathway for flow of electrically conducting liquid therethrough. The liquid is directed past the surface of the return electrode and over the active electrode to thereby provide a return current flow path between the target tissue site and the return 35 array disposed transversely to the axis of the probe;

The active and return electrodes will preferably be configured such that, upon the application of a sufficient highfrequency voltage, a thin layer of the electrically conducting layer is vaporized over at least a portion of the active 40 electrode(s) in the region between the active electrode(s) and the target tissue. To accomplish this, the active electrode(s) will be configured such that high electric field densities form at the distal tips of the active electrode(s). By way of example, the present invention may utilize an electrode array 45 of electrode terminals flush with or recessed from or extending from the distal end of the probe. The electrode terminals will preferably have a sufficiently small area, extension (or recession) length from the probe and sharp edges and/or surface asperities such that localized high current densities 50 are promoted on the electrode terminals which, in turn, lead to the formation of a vaporized layer or region over at least a portion of the active electrode(s) followed by the high electric field induced breakdown (i.e., ionization) of ionizable species within the vapor layer or region and the 55 emission of photon and/or electrons of sufficient energy to cause dissociation of molecules within the target tissue.

In an exemplary embodiment, the active electrode(s) are sized and arranged to create localized sources of energy (e.g., point sources or sources with a relatively small effec- 60 tive radius) at the distal tips of the electrode(s) when a sufficiently high frequency voltage is applied to the return and active electrodes. These small localized sources generate intense energy at the distal ends of the electrodes for molecular dissociation or ablation of tissue in contact with 65 or in close proximity to the electrode tips. In addition, since the localized sources have relatively small radii, the energy

flux decreases with the square of the distance from the localized sources so that the tissue at greater distances from the electrode tips are not significantly affected by the energy

A further understanding of the nature and advantages of the invention will become apparent by reference to the remaining portions of the specification and drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of the electrosurgical system including an electrosurgical probe, an electrically conducting liquid supply and an electrosurgical power supply constructed in accordance with the principles of the present invention:

FIG. 2A is an enlarged, cross-sectional view of the distal tip of the electrosurgical probe of FIG. 1 illustrating an electrode arrangement suitable for rapid cutting and ablation of tissue structures;

FIG. 2B is an enlarged end view of the distal tip of the electrosurgical probe of FIG. 1;

FIG. 2C is a cross-sectional view of the proximal end of the electrosurgical probe, illustrating an arrangement for coupling the probe to the electrically conducting liquid supply of FIG. 1;

FIG. 3 is a detailed cross-sectional view of an alternative embodiment of the electrosurgical probe of FIG. 1;

FIG. 4 is an end view of the distal end of the electrosurgical probe of FIG. 3:

PIG. 5 is an end view of an another embodiment of the electrosurgical probe of FIG. 1;

FIG. 6 is a partial cross-sectional side view of a further embodiment of the electrosurgical probe with the electrode

FIG. 7 is a partial front cross-sectional view of an electrosurgical probe and an electrically conductive liquid supply shaft illustrating use of the probe and the shaft in ablating target tissue;

FIG. 8 is an enlarged, cross-sectional view of the distal tip of yet another embodiment of the electrosurgical probe of FIG. 1:

FIG. 9 is a detailed end view of the probe of FIG. 8;

FIG. 10 is a side view of an electrosurgical probe having a shaft with an angled distal portion;

FIG. 11 is a side view of an electrosurgical probe having a shaft with a perpendicular distal portion:

FIG. 12 is a schematic view of an electrosurgical probe having two screwdriver-shaped electrodes extending from the distal ead:

FIG. 13 is an end view of the probe of FIG. 12;

FIG. 14 illustrates use of the probe of FIG. 12 for the rapid cutting of tissue;

FIG. 15 is a cross-sectional view of the distal tip of the electrosurgical probe, illustrating electric field lines between the active and return electrodes;

FIG. 16 is an enlarged cross-sectional view of the distal tip of the probe of FIG. 15, illustrating a vapor layer formed between the active electrodes and the target tissue;

FIG. 17 is a cross-sectional view of an alternative electrosurgical probe for applying high frequency voltage to epidermal tissue layers;

FIG. 18 is a sectional view of the human heart, illustrating the electrosurgical probe within the ventricular cavity for performing a transmyocardial revascularization procedure;

FIG. 19 is a cross-sectional view of the probe boring a channel through the ventricular wall;

FIG. 20 depicts an alternative embodiment of the probe of FIG. 19 having an inner lumen for aspirating fluid and gases from the transmyocardial channel;

FIG. 21 depicts a distal portion of an alternative embodiment of the probe of FIGS. 2A-2C incorporating a single electrode with a tubular geometry;

FIG. 22 is a cross-sectional view of the distal end of the probe of FIG. 21:

FIG. 23 is a side cross-sectional view of a distal portion of a further embodiment of the probe of FIGS. 2A-2C incorporating a multiplicity of electrodes which converge to a single electrode lead; and

FIG. 24 is a side cross-sectional view of a distal portion of yet another embodiment of the probe of FIGS. 2A-2C incorporating a single electrode connected to a single electrode lead.

DESCRIPTION OF THE PREFERRED **EMBODIMENT**

The present invention provides a system and method for selectively applying electrical energy to a target location within or on a patient's body, such as solid tissue or the like, 25 particularly including gingival tissues and mucosal tissues located in the mouth or epidermal tissue on the outer skin. In addition, tissues which may be treated by the system and method of the present invention include tumors, abnormal tissues, and the like. The invention may also be used for 30 canalizing or boring channels or holes through tissue, such as the ventricular wall during transmyocardial revascularization procedures. For convenience, the remaining disclosure will be directed specifically to the cutting, shaping or ablation of gingival or mucosal tissue in oral surgical procedures, the surface tissue ablation of the epidermis in dermatological procedures and the canalization of channels through the myocardium of the heart, but it will be appreciated that the system and method can be applied equally well to procedures involving other tissues of the body, as well as to other procedures including open surgery, laparoscopic surgery, thoracoscopic surgery, and other endoscopic surgical procedures.

In addition, the present invention is particularly useful in procedures where the tissue site is flooded or submerged 45 with an electrically conducting fluid, such as isotonic saline. Such procedures, e.g., arthroscopic surgery and the like, are described in detail in co-pending PCT International Application, U.S. National Phase Serial No. PCT/US94/ 05168, filed on May 10, 1994, the complete disclosure of 50 which has been incorporated herein by reference.

The present invention may use a single active electrode or an electrode array distributed over a distal contact surface of a probe. The electrode array usualty includes a plurality of independently current-limited and/or power-controlled elec- 55 trode terminals to apply electrical energy selectively to the target tissue while limiting the unwanted application of electrical energy to the surrounding tissue and environment resulting from power dissipation into surrounding electrically conductive liquids, such as blood, normal saline, and the like. The electrode terminals may be independently current-limited by isolating the terminals from each other and connecting each terminal to a separate power source that is isolated from the other electrode terminals. Alternatively, the electrode terminals may be connected to each other at 65 either the proximal or distal ends of the probe to form a single wire that couples to a power source.

The electrosurgical probe will comprise a shaft having a proximal end and a distal end which supports an active electrode. The shaft may assume a wide variety of configurations, with the primary purpose being to mechanically support the active electrode and permit the treating physician to manipulate the electrode from a proximal end of the shaft. Usually, the shaft will be a narrow-diameter rod or tube, more usually having dimensions which permit it to be introduced into a body cavity, such as the mouth or the 10 abdominal cavity, through an associated trocar or cannula in a minimally invasive procedure, such as arthroscopic, laparoscopic, thoracoscopic, and other endoscopic procedures. Thus, the shaft will typically have a leagth of at least 5 cm for oral procedures and at least 10 cm, more typically being 20 cm, or longer for endoscopic procedures. The shaft will typically have a diameter of at least 1 mm and frequently in the range from 1 to 10 mm. Of course, for dermatological procedures on the outer skin, the shaft may have any suitable length and diameter that would facilitate 20 handling by the surgeon.

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The shaft may be rigid or flexible, with flexible shafts optionally being combined with a generally rigid external tube for mechanical support. Flexible shafts may be combined with pull wires, shape memory actuators, and other known mechanisms for effecting selective deflection of the distal end of the shaft to facilitate positioning of the electrode array. The shaft will usually include a plurality of wires or other conductive elements running axially therethrough to permit connection of the electrode array to a connector at the proximal ead of the shaft. Specific shaft designs will be described in detail in connection with the figures hereinafter.

The circumscribed area of the electrode array is in the range from 0.25 mm² to 75 mm², preferably from 0.5 mm² to 40 mm², and will usually include at least two isolated electrode terminals, more usually at least four electrode terminals, preferably at least six electrode terminals, and often 50 or more electrode terminals, disposed over the distal contact surfaces on the shaft. By bringing the electrode array(s) on the contact surface(s) in close proximity with the target tissue and applying high frequency voltage between the array(s) and an additional common or return electrode in direct or indirect contact with the patient's body, the target tissue is selectively ablated or cut, permitting selective removal of portions of the target tissue while desirably minimizing the depth of necrosis to surrounding tissue. In particular, this invention provides a method and apparatus for effectively ablating and cutting tissue which may be located in close proximity to other critical organs, vessels or structures (e.g., teeth, bone) by simultaneously (1) causing electrically conducting liquid to flow between the common and active electrodes, (2) applying electrical energy to the target tissue surrounding and immediately adjacent to the tip of the probe. (3) bringing the active electrode(s) in close proximity with the target tissue using the probe itself, and (4) optionally moving the electrode array axially and/or transversely over the tisso

In one configuration, each individual electrode terminal in the electrode array is electrically insulated from all other electrode terminals in the array within said probe and is connected to a power source which is isolated from each of the other electrodes in the array or to circuitry which limits or interrupts current flow to the electrode when low resistivity material (e.g., blood or electrically conductive saline irrigant) causes a lower impedance path between the common electrode and the individual electrode terminal. The isolated power sources for each individual electrode may be separate power supply circuits having internal impedance characteristics which limit power to the associated electrode terminal when a low impedance return path is encountered, may be a single power source which is connected to each of the electrodes through independently actuatable switches or may be provided by independent current limiting elements, such as inductors, capacitors, resistors and/or combinations thereof. The current limiting elements may be provided in the probe, connectors, cable, controller or along the conductive path from the controller to the distal tip. Alternatively, the resistance and/or capacitance may occur on the surface of the active electrode(s) due to oxide layers which form selected electrode terminals (e.g., titanium or a resistive coating on the surface of metal, such as platinum)

The tip region of the probe may be composed of many independent electrode terminals designed to deliver electri- 15 cal energy in the vicinity of the tip. The selective application of electrical energy to the target tissue is achieved by connecting each individual electrode terminal and the common electrode to a power source having independently controlled or current limited channels. The common electrode may be a tubular member of conductive material proximal to the electrode array at the tip which also serves as a conduit for the supply of the electrically conducting liquid between the active and common electrodes. The application of high frequency voltage between the common 25 electrode and the electrode array results in the generation of high electric field intensities at the distal tips of the electrodes with conduction of high frequency current from each individual electrode terminal to the common electrode. The current flow from each individual electrode terminal to the 30 common electrode is controlled by either active or passive means, or a combination thereof, to deliver electrical energy to the target tissue while minimizing energy delivery to surrounding (non-target) tissue and any conductive fluids which may be present (e.g., blood, electrolytic irrigants such 35 as saline, and the like).

In a preferred aspect, this invention takes advantage of the differences in electrical resistivity between the target tissue (e.g., gingiva, muscle, fascia, tumor, epidermal, heart or other tissue) and the surrounding conductive liquid (e.g., 40 isotonic saline irrigant). By way of example, for any selected level of applied voltage, if the electrical conduction path between the common electrode and one of the individual electrode terminals within the electrode array is isotonic saline irrigant liquid (having a relatively low electrical impedance), the current control means connected to the individual electrode will limit current flow so that the heating of intervening conductive liquid is minimized. On the other hand, if a portion of or all of the electrical conduction path between the common electrode and one of 50 the individual electrode terminals within the electrode array is gingival tissue (having a relatively higher electrical impedance), the current control circuity or switch connected to the individual electrode will allow current flow sufficient for the deposition of electrical energy and associ- 55 ated ablation or electrical breakdown of the target tissue in the immediate vicinity of the electrode surface.

The application of a high frequency voltage between the common or return electrode and the electrode array for appropriate time intervals effects ablation, cutting or reshaping of the target tissue. The tissue volume over which energy is dissipated (i.e., a high voltage gradient exists) may be precisely controlled, for example, by the use of a multiplicity of small electrodes whose effective diameters range from about 2 mm to 0.01 mm, preferably from about 1 mm to 0.05 65 mm, and more preferably from about 0.5 mm to 0.1 mm. Electrode areas for both circular and non-circular terminals

will have a contact area (per electrode) below 5 mm², preferably being in the range from 0.0001 mm² to 1 mm², and more preferably from 0.005 mm² to 0.5 mm². The use of small diameter electrode terminals increases the electric field intensity and reduces the extent or depth of tissue necrosis as a consequence of the divergence of current flux lines which emanate from the exposed surface of each electrode terminal. Energy deposition in tissue sufficient for irreversible damage (i.e., necrosis) has been found to be limited to a distance of about one-half to one electrode diameter. This is a particular advantage over prior electrodes where the depth of tissue necrosis may not be sufficiently limited.

In previous electrosurgical devices, increased power application and ablation rates have been achieved by increasing the electrode area. Surprisingly, with the present invention, it has been found that the total electrode area can be increased (to increase power delivery and ablation rate) without increasing the depth of necrosis by providing multiple small electrode terminals. Preferably, the terminals will be spaced-apart by a distance in the range from about one-half diameter to one diameter for optimum power delivery, as discussed below. The depth of necrosis may be further controlled by switching the applied voltage off and on to produce pulses of current, the pulses being of sufficient duration and associated energy density to effect abiation and/or cutting while being turned off for periods sufficiently long to allow for thermal relaxation between energy pulses. In this manner, the energy pulse duration and magnitude and the time interval between energy pulses are selected to achieve efficient rates of tissue ablation or cutting while allowing the temperature of the treated zone of tissue to "relax" or return to normal physiologic temperatures (usually to within 10° C. of normal body temperature [37° C.]. preferably to within 5° C.) before the onset of the next energy (current) pulse.

In addition to the above described methods, the applicant has discovered another mechanism for ablating tissue while minimizing the depth of accrosis. This mechanism involves applying a high frequency voltage between the active electrode surface and the return electrode to develop high electric field intensities in the vicinity of the target tissue site. The high electric field intensities lead to electric field induced molecular breakdown of target tissue through molecular dissociation (rather than thermal evaporation or carbonization). In other words, the tissue structure is volumetrically removed through molecular disintegration of complex organic molecules into non-viable atoms and molecules, such as hydrogen, oxides of carbon, hydrocarbons and nitrogen compounds. This molecular disintegration completely removes the tissue structure, as opposed to transforming the tissue material from a solid form directly to a vapor form, as is typically the case with ablation.

The high electric field intensities may be generated by applying a high frequency voltage that is sufficient to vaporize the electrically conducting liquid over at least a portion of the active electrode(s) in the region between the distal tip of the active electrode and the target tissue. Since the vapor layer or vaporized region has a relatively high electrical impedance, it increases the voltage differential between the active electrode tip and the tissue and causes ionization within the vapor layer due to the presence of an ionizable species (e.g., sodium when isotonic saline is the electrically conducting fluid). This ionization, under optimal conditions, induces the discharge of energetic electrons and photons from the vapor layer and to the surface of the target

tissue. This energy may be in the form of energetic photons (e.g., ultraviolet radiation), energetic particles (e.g., electrons) or a combination thereof.

The necessary conditions for forming a vapor layer near the active electrode tip(s), ionizing the atom or atoms within the vapor layer and inducing the discharge of energy from plasma within the vapor layer will depend on a variety of factors, such as: the number of electrode terminals; electrode size and spacing; electrode surface area; asperities and sharp edges on the electrode surfaces; electrode materials; applied voltage and power; current limiting means, such as inductors; electrical conductivity of the fluid in contact with the electrodes; density of the fluid; and other factors. Based on initial experiments, applicants believe that the ionization of atoms within the vapor layer produced in isotonic saline (containing sodium chloride) leads to the generation of energetic photons having wavelengths, by way of example, in the range of 306 to 315 nanometers (ultraviolet spectrum) and 588 to 590 nanometers (visible spectrum). In addition, the free electrons within the ionized vapor layer are accelcrated in the high electric fields near the electrode tip(s). When the density of the vapor layer (or within a bubble formed in the electrically conducting liquid) becomes sufficiently low (i.e., less than approximately 1020 atoms/cm2 for aqueous solutions), the electron mean free path increases to enable subsequently injected electrons to cause impact 25 ionization within these regions of low density (i.e., vapor layers or bubbles). Energy evolved by the energetic electrons (e.g., 4 to 5 eV) can subsequently bombard a molecule and break its bonds, dissociating a molecule into free

species. The photon energy produces photoablation through photochemical and/or photothermal processes to disintegrate tissue thicknesses as small as several cell layers of tissue at the target site. This photoablation is a "cold" ablation, which 35 means that the photon energy transfers very little heat to tissue beyond the boundaries of the region of tissue ablated. The cold ablation provided by photon energy can be precisely controlled to only affect a thin layer of cells without heating or otherwise damaging surrounding or underlying 40 cells. The depth of necrosis will be typically be about 0 to 400 microns and usually 10 to 200 microns. Applicants believe that the "fragments" of disintegrated tissue molecules carry away much of the energy which is deposited on the surface of the target tissue, thereby allowing molecular disintegration of tissue to occur while limiting the amount of heat transfer to the surrounding tissue.

radicals, which then combine into final gaseous or liquid 30

In addition, other competing mechanisms may be contributing to the ablation of tissue. For example, tissue destruction or ablation may also be caused by dielectric 50 breakdown of the tissue structural elements or cell membranes from the highly concentrated intense electric fields at the tip portions of the electrode(s). According to the teachings of the present invention, the active electrode(s) are conditions of applied voltage, cause the formation of a vaporized region or layer over at least a portion of the surface of the active electrode(s). This layer or region of vaporized electrically conducting liquid creates the conditions necessary for ionization within the vaporized region or 60 layer and the generation of energetic electrons and photons. In addition, this layer or region of vaporized electrically conducting liquid provides a high electrical impedance between the electrode and the adjacent tissue so that only low levels of current flow across the vaporized layer or 65 region into the tissue, thereby minimizing joulean heating in, and associated necrosis of, the tissue.

As discussed above, applicants have found that the density of the electrically conducting liquid at the distal tips of the active electrodes should be less than a critical value to form a suitable vapor layer. For aqueous solutions, such as water or isotonic saline, this upper density limit is approximately 1020 atoms/cm3, which corresponds to about 3×10-3 grams/cm3. Applicant's also believe that once the density in the vapor layer reaches a critical value (e.g., approximately 1020 atoms/cm3 for aqueous solutions), electron avalanche 10 occurs. The growth of this avalanche is retarded when the space charge generated fields are on the order of the external field. Spatial extent of this region should be larger than the distance required for an electron avalanche to become critical and for an ionization front to develop. This ionization front develops and propagates across the vapor layer via a sequence of processes occurring in the region ahead of the front, viz, heat by electron injection, lowering of the local liquid density below the critical value and avalanche growth of the charged particle concentration.

Electrons accelerated in the electric field within the vapor layer will apparently become trapped after one or a few scatterings. These injected electrons serve to create or sustain a low density region with a large mean free path to enable subsequently injected electrons to cause impact ionization within these regions of low density. The energy evolved at each recombination is on the order of half of the energy band gap (i.e., 4 to 5 eV). It appears that this energy can be transferred to another electron to generate a highly energetic electron. This second, highly energetic electron may have sufficient energy to bombard a molecule to break its bonds, i.e., dissociate the molecule into free radicals.

The electrically conducting liquid should have a threshold conductivity in order to suitably ionize the vapor layer for the inducement of energetic electrons and photons. The electrical conductivity of the fluid (in units of milliSieman per centimeter or mS/cm) will usually be greater than 0.2 mS/cm, preferably will be greater than 2 mS/cm and more preferably greater than 10 mS/cm. In an exemplary embodiment, the electrically conductive fluid is isotonic saline, which has a conductivity of about 17 mS/cm. The electrical conductivity of the channel trailing the ionization front should be sufficiently high to maintain the energy flow required to heat the liquid at the ionization front and maintain its density below the critical level. In addition, when the electrical conductivity of the liquid is sufficiently high, ionic pre-breakdown current levels (i.e., current levels prior to the initiation of ionization within the vapor layer) are sufficient to also promote the initial growth of bubbles within the electrically conducting liquid (i.e., regions whose density is less than the critical density).

Asperities on the surface of the active electrode(s) appear to promote localized high current densities which, in turn, promote bubble nucleation at the site of the asperities whose enclosed density (i.e., vapor density) is below the critical sized and have exposed surfaces areas which, under proper 55 density to initiate ionization breakdown within the bubble. Hence, a specific configuration of the present invention creates regions of high current densities on the tips of the electrode(s) (i.e., the surface of the electrode(s) which are to engage and ablate or cut tissue). Regions of high current densities can be achieved via a variety of methods, such as producing sharp edges and corners on the distal tips of the electrodes or vapor blasting, chemically etching or mechanically abrading the distal end faces of the active electrodes to produce surface asperities thereon. Alternatively, the electrode terminals may be specifically designed to increase the edge/surface area ratio of the electrode terminals. For example, the electrode terminal(s) may be hollow tubes having a distal, circumferential edge surrounding an opening. The terminals may be formed in an array as described above or in a series of concentric terminals on the distal end of the probe. High current densities will be generated around the circumferential edges of the electrode terminals to promote nucleate bubble formation.

The voltage applied between the common electrode and the electrode array will be at high or radio frequency, typically between about 5 kHz and 20 MHz, usually being between about 30 kHz and 2.5 MHz, and preferably being 10 between about 50 kHz and 400 kHz. The RMS (root mean square) voltage applied will usually be in the range from about 5 volts to 1000 volts, preferably being in the range from about 50 volts to 800 volts, and more preferably being in the range from about 100 volts to 400 volts. These frequencies and voltages will result in peak-to-peak voltages and currents that are sufficient to vaporize the electrically conductive liquid and, in turn, create the conditions within the vaporized region which result in high electric fields and emission of energetic photons and/or electrons to ablate 20 tissue. Typically, the peak-to-peak voltage will be in the range of 200 to 2000 volts and preferably in the range of 300 to 1400 volts and more preferably in the range of 700 to 900

As discussed above, the voltage is usually delivered in a 25 series of voltage pulses with a sufficiently high frequency (e.g., on the order of 5 kHz to 20 MHz) such that the voltage is effectively applied continuously (as compared with e.g., lasers claiming small depths of necrosis, which are generally pulsed about 10 to 20 Hz). In addition, the pulsed duty cycle 30 (i.e., cumulative time in any one-second interval that energy is applied) is on the order of about 50% for the present invention, as compared with lasers which typically have a

duty cycle of about 0.0001%.

Applicants believe that the present invention is capable of 35 obtaining high ablation rates with effectively continuous mode operation and high duty cycles because the source of energy emitted from the edges and tips of the small electrode terminals is effectively a point source or a source having a relatively small effective radius. As is well known in the art. 40 the flux emitted from a point source and crossing a boundary in spherical space generally decreases as the square of distance from the source. Thus, the "energy source" of the present invention (i.e., the intense electric field, the energetic photons or the energetic electrons) is highly concentrated by 45 virtue of the geometry of the emitting electrodes and the source of energy at the tips of the electrodes. As a result, only those regions or areas that are very close to the electrode tips or source will be exposed to high energy fluxes. Consequently, ablation will typically only occur in 50 skill of the art. tissue layers effectively in contact or in very close proximity with the tips of the electrodes. The tissue at greater distances from the electrode tips are not significantly affected since the energy flux is too low at these distances to irreversibly affect or damage tissue.

Usually, the current level will be selectively limited or controlled and the voltage applied will be independently adjustable, frequently in response to the resistance of tissues and/or fluids in the pathway between an individual electrode may be in response to a temperature control means which maintains the target tissue temperature with desired limits at the interface between the electrode arrays and the target tissue. The desired tissue temperature along a propagating surface just beyond the region of ablation will usually be in 65 the range from about 40° C. to 100° C., and more usually from about 50° C. to 60° C. The tissue being ablated (and

hence removed from the operation site) immediately adjacent the electrode array may reach even higher temperatures.

The preferred power source of the present invention delivers a high frequency current selectable to generate average power levels ranging from tens of milliwatts to tens of watts per electrode, depending on the target tissue being ablated, the rate of ablation desired or the maximum allowed temperature selected for the probe tip. The power source allows the user to select the current level according to the specific requirements of a particular oral surgery, dermatological procedure, open surgery or other endoscopic surgery procedure.

The power source may be current limited or otherwise controlled so that undesired heating of electrically conductive fluids or other low electrical resistance media does not occur. In a presently preferred embodiment of the present invention, current limiting inductors are placed in series with each independent electrode terminal, where the inductance of the inductor is in the range of 10 uH to 50,000 uH. depending on the electrical properties of the target tissue, the desired ablation rate and the operating frequency. Alternatively, capacitor-inductor (LC) circuit structures may be employed, as described previously in co-pending PCT application No. PCT/US94/05168, the complete disclosure of which is incorporated herein by reference. Additionally, current limiting resistors may be selected. Preferably, these resistors will have a large positive temperature coefficient of resistance so that, as the current level begins to rise for any individual electrode in contact with a low resistance medium (e.g., saline irrigant), the resistance of the current limiting resistor increases significantly, thereby minimizing the power delivery from said electrode into the low resistance medium (e.g., saline irrigant).

As an alternative to such passive circuit structures, regulated current flow to each electrode terminal may be provided by a multi-channel power supply. A substantially constant current level for each individual electrode terminal within a range which will limit power delivery through a low resistance path, e.g., isotonic saline irrigant, and would be selected by the user to achieve the desired rate of cutting or ablation. Such a multi-channel power supply thus provides a substantially constant current source with selectable current level in series with each electrode terminal, wherein all electrodes will operate at or below the same, user selectable maximum current level. Current flow to all electrode terminals could be periodically sensed and stopped if the temperature measured at the surface of the electrode array exceeds user selected limits. Particular control system designs for implementing this strategy are well within the

Yet another alternative involves the use of one or several power supplies which allow one or several electrodes to be simultaneously energized and which include active control means for limiting current levels below a preselected maxi-55 mum level. In this arrangement, only one or several electrodes would be simultaneously energized for a brief period. Switching means would allow the next one or several electrodes to be energized for a brief period. By sequentially energizing one or several electrodes, the interaction between and the common electrode. Also, the applied current level 60 adjacent electrodes can be minimized (for the case of energizing several electrode positioned at the maximum possible spacing within the overall envelope of the electrode array) or eliminated (for the case of energizing only a single electrode at any one time). As before, a resistance measurement means may be employed for each electrode prior to the application of power wherein a (measured) low resistance (below some preselected level) will prevent that electrode

from being energized during a given cycle. By way of example, the sequential powering and control scheme of the present invention would function in a manner similar to an automobile distributor. In this example, an electrical contact rotates past terminals connected to each spark plug. In this example, each spark plug corresponds to the exposed surface of each of the electrodes. In addition, the present invention includes the means to measure the resistance of the medium in contact with each electrode and cause voltage to be applied only if the resistance exceeds a preselected level.

It should be clearly understood that the invention is not limited to electrically isolated electrode terminals, or even to a plurality of electrode terminals. For example, the array of active electrode terminals may be connected to a single lead that extends through the probe shaft to a power source of high frequency current. Alternatively, the probe may incorporate a single electrode that extends directly through the probe shaft or is connected to a single lead that extends to the power source.

The active electrode(s) are formed over a contact surface on the shaft of the electrosurgical probe. The common (return) electrode surface will be recessed relative to the distal end of the probe and may be recessed within the conduit provided for the introduction of electrically conducting liquid to the site of the target tissue and active electrode(s). In the exemplary embodiment, the shaft will be cylindrical over most of its length, with the contact surface being formed at the distal end of the shaft. In the case of endoscopic applications, the contact surface may be recessed since it helps protect and shield the electrode terminals on the surface while they are being introduced, particularly while being introduced through the working channel of a trocar channel or a viewing scope.

The area of the contact surface can vary widely, and the contact surface can assume a variety of geometries, with 35 particular areas in geometries being selected for specific applications. Active electrode contact surfaces can have areas in the range from 0.25 mm² to 50 mm², usually being from 1 mm2 to 20 mm2. The geometries can be planar, concave, convex, hemispherical, conical, linear "in-line" array or virtually any other regular or irregular shape. Most commonly, the active electrode(s) will be formed at the distal tip of the electrosurgical probe shaft, frequently being planar, disk-shaped, or hemispherical surfaces for use in reshaping procedures or being linear arrays for use in 45 cutting. Alternatively or additionally, the active electrode(s) may be formed on lateral surfaces of the electrosurgical probe shaft (e.g., in the manner of a spatula), facilitating access to certain body structures in electrosurgical proce-

During the surgical procedure, the distal end of the probe or the active electrode(s) will be maintained at a small distance away from the target tissue surface. This small spacing allows for the continual resupply of electrically conducting liquid into the interface between the active 55 electrode(s) and the target tissue surface. This continual resupply of the electrically conducting liquid helps to ensure that the thin vapor layer will remain between active electrode(s) and the tissue surface. In addition, dynamic movement of the active electrode(s) over the tissue site allows the electrically conducting liquid to cool the tissue surrounding recently ablated areas to minimize thermal damage to this surrounding tissue. Typically, the active electrode(s) will be about 0.02 to 2 mm from the target tissue and preferably about 0.05 to 0.5 mm during the ablation process. One method of maintaining this space is to translate and/or rotate the probe transversely relative to the tissue, i.e.,

a light brushing motion, to maintain a thin vaporized layer or region between the active electrode and the tissue. Of course, if coagulation of a deeper region of tissue is necessary (e.g., for scaling a bleeding vessel imbedded within the tissue), it may be desirable to press the active electrode against the tissue to effect joulean heating thereia.

Referring to the drawings in detail, wherein like numerals indicate like elements, an electrostrigical system 11 is shown constructed according to the principles of the present invention. Electrostrigical system 11 generally comprises an electrostrigical probe 10 connected to a power supply 28 for providing high frequency voltage to a target tissue 52 and a liquid source 21 for supplying electrically conducting fluid 50 to probe 10.

In an exemplary embodiment as shown in FIG. 1, electrosurgical probe 10 includes an elongated shaft 13 which may be flexible or rigid, with flexible shafts optionally including support cannulas or other structures (not shown). Probe 10 includes a connector 19 at its proximal end and an array 12 of electrode terminals 58 disposed on the distal tip of shaft 13. A connecting cable 34 has a handle 22 with a connector 20 which can be removably connected to connector 19 of probe 14. The proximal portion of cable 34 has a connector 26 to couple probe 10 to power supply 28. The electrode terminals 58 are electrically isolated from each other and each of the terminals 58 is connected to an active or passive control network within power supply 28 by means of a plurality of individually insulated conductors 42 (see FIG. 2C). Power supply 28 has a selection means 30 to change the applied voltage level. Power supply 28 also includes means for energizing the electrodes 58 of probe 10 through the depression of a pedal 39 in a foot pedal 37 positioned close to the user. The foot pedal 37 may also include a second pedal (not shown) for remotely adjusting the energy level applied to electrodes 58. The specific design of a power supply which may be used with the electrosurgical probe of the present invention is described in parent application PCI US 94/051168, the full disclosure of which has previously been incorporated herein by reference.

Referring to FIGS. 2A and 2B, the electrically isolated electrode terminals 58 are spaced-apart over an electrode array surface 82. The electrode array surface 82 and individual electrode terminals 58 will usually have dimensions within the ranges set forth above. In the preferred embodiment, the electrode array surface 82 has a circular cross-sectional shape with a diameter D (FIG. 2B) in the range from 0.3 mm to 10 mm. Electrode array surface 82 may also have an oval shape, having a length L in the range of 1 mm to 20 mm and a width W in the range from 0.3 mm to 7 mm, as shown in FIG. 5. The individual electrode terminals 58 will protrude over the electrode array surface 82 by a distance (H) from 0 mm to 2 mm, preferably from 0 mm to 1 mm (see FIG. 3).

It should be noted that the electrode terminals may be flush with the electrode array surface 82, or the terminals may be recessed from the surface. For example, in dermatological procedures, the electrode terminals 58 may be recessed by a distance from 0.01 mm to 1 mm, preferably 0.01 mm to 0.2 mm. In one embodiment of the invention, the electrode terminals are axially adjustable relative to the electrode array surface 82 so that the surgeon can adjust the distance between the surface and the electrode terminals.

The electrode terminals 58 are preferably composed of a 65 refractory, electrically conductive metal or alloy, such as platinum, titanium, tantalum, tungsten and the like. As shown in FIG. 2B, the electrode terminals 58 are anchored

in a support matrix 48 of suitable insulating material (e.g., ceramic or glass material, such as alumina, zirconia and the like) which could be formed at the time of manufacture in a flat, hemispherical or other shape according to the requirements of a particular procedure. The preferred support matrix material is alumina, available from Kyocera Industrial Ceramics Corporation, Elkgrove, Ill., because of its high thermal conductivity, good electrically insulative properties, high flexural modulus, resistance to carbon tracking, biocompatibility, and high melting point.

As shown in FIG. 2A, the support matrix 48 is adhesively joined to a tubular support member 78 that extends most or all of the distance between matrix 48 and the proximal end of probe 10. Tubular member 78 preferably comprises an electrically insulating material, such as an epoxy, injection moldable plastic or silicone-based material. In a preferred construction technique, electrode terminals 58 extend through pre-formed openings in the support matrix 48 so that they protrude above electrode array surface 82 by the desired distance H (FIG. 3). The electrodes may then be bonded to the distal surface 82 of support matrix 48, typically by an inorganic scaling material 80. Scaling material 80 is selected to provide effective electrical insulation, and good adhesion to both the ceramic matrix 48 and the platinum or titanium electrode terminals. Scaling material 80 additionally should have a compatible thermal expansion coefficient and a melting point well below that of platinum or titanium and ahumina or zirconia, typically being a glass or glass ceramic.

In the embodiment shown in FIGS. 2A and 2B, probe 10 includes a return electrode 56 for completing the current path between electrode terminals 58 and power supply 28. Return electrode 56 is preferably an annular member positioned around the exterior of shaft 13 of probe 10. Return electrode 56 may fully or partially circumscribe tubular 35 support member 78 to form an annular gap 54 therebetween for flow of electrically conducting liquid 50 therethrough, as discussed below. Gap 54 preferably has a width in the range of 0.15 mm to 4 mm. Return electrode 56 extends from the proximal end of probe 10, where it is suitably connected to 40 power supply 28 via connectors 19, 20, to a point slightly proximal of electrode array surface 82, typically about 0.5 to 10 mm and more preferably about 1 to 10 mm.

Return electrode 56 is disposed within an electrically insulative jacket 18, which is typically formed as one or 4 more electrically insulative sheaths or coatings, such as polytetrafluoroethylene, polyimide, and the like. The provision of the electrically insulative jacket 18 over return electrode 56 prevents direct electrical contact between return electrode 56 and any adjacent body structure or the surgeon. 50 Such direct electrical contact between a body structure (e.g., tendon) and an exposed common electrode member 56 could result in unwanted heating and necrosis of the structure at the point of contact causing necrosis.

cally conductive material, usually metal, which is selected from the group consisting of stainless steel alloys, platinum or its alloys, titanium or its alloys, molybdenum or its alloys, and nickel or its alloys. The return electrode 56 may be electrode terminals 58 to minimize any potential for corrosion or the generation of electrochemical potentials due to the presence of dissimilar metals contained within an electrically conductive fluid 50, such as isotonic saline (discussed in greater detail below).

As shown in FIG. 2A, return electrode 56 is not directly connected to electrode terminals 58. To complete this cur-

rent path so that terminals 58 are electrically connected to return electrode 56 via target tissue 52, electrically conducting liquid 50 (e.g., isotonic saline) is caused to flow along liquid paths 83. A liquid path 83 is formed by annular gap 54 between outer return electrode 56 and tubular support member 78. An additional liquid path 83 may be formed between an inner lumen 57 within an inner tubular member 59. However, it is generally preferred to form the liquid path 83 near the perimeter of the probe so that the electrically conducting liquid tends to flow radially inward towards the target site 88 (this preferred embodiment is illustrated in FIGS. 8-19). In the embodiment shown in FIGS. 2-5, the liquid flowing through inner lumen 57 may tend to splash radially outward, drawing electrical current therewith and 15 potentially causing damage to the surrounding tissue.

The electrically conducting liquid 50 flowing through fluid paths 83 provides a pathway for electrical current flow between target tissue 52 and return electrode 56, as illustrated by the current flux lines 60 in FIG. 2A. When a voltage difference is applied between electrode array 12 and return electrode 56, high electric field intensities will be generated at the distal tips of terminals 58 with current flow from array 12 through the target tissue to the return electrode, the high electric field intensities causing ablation of tissue 52 in zone 88.

FIGS. 2C, 3 and 4 illustrate an alternative embodiment of electrosurgical probe 10 which has a return electrode 55 positioned within tubular member 78. Return electrode 55 is preferably a tubular member defining an inner lumen 57 for allowing electrically conducting liquid 50 (e.g., isotonic saline) to flow therethrough in electrical contact with return electrode 55. In this embodiment, a voltage difference is applied between electrode terminals 58 and return electrode 55 resulting in electrical current flow through the electrically conducting liquid 50 as shown by current flux lines 60 (FIG. 3). As a result of the applied voltage difference and concomitant high electric field intensities at the tips of electrode terminals 58, tissue 52 becomes ablated or transected in zone

FIG. 2C illustrates the proximal or connector end 70 of probe 10 in the embodiment of FIGS. 3 and 4. Connector 19 comprises a plurality of individual connector pins 74 positioned within a housing 72 at the proximal end 70 of probe 10. Electrode terminals 58 and the attached insulating conductors 42 extend proximally to connector pins 74 in connector housing 72. Return electrode 55 extends into housing 72, where it bends radially outward to exit probe 10. As shown in FIGS. 1 and 2C, a liquid supply tube 15 removably couples liquid source 21. (e.g., a bag of fluid elevated above the surgical site or having a pumping device), with return electrode 55. Preferably, an insulating jacket 14 covers the exposed partions of electrode 55. One of the connector pins 76 is electrically connected to return electrode 55 to couple electrode 55 to power supply 28 via cable 34. A manual Return electrode 56 is preferably formed from an electri- 55 control valve 17 may also be provided between the proximal end of return electrode 55 and supply tube 15 to allow the surgical team to regulate the flow of electrically conducting liquid 50.

FIG. 6 illustrates another embodiment of probe 10 where composed of the same metal or alloy which forms the 60 the distal portion of shaft 13 is bent so that electrode terminals extend transversely to the shaft. Preferably, the distal portion of shaft 13 is perpendicular to the rest of the shaft so that electrode array surface 82 is generally parallel to the shaft axis. as shown in FIG. 6. In this embodiment, return electrode 55 is mounted to the outer surface of shaft 13 and is covered with an electrically insulating jacket 18. The electrically conducting fluid 50 flows along flow path 83

through return electrode 55 and exits the distal end of electrode 55 at a point proximal of electrode surface 82. The fluid is directed exterior of shaft to electrode surface 82 to create a return current path from electrode terminals 58, through target tissue 52, to return electrode 55, as shown by 5 current flux lines 60.

FIG. 7 illustrates another embodiment of the invention where electrosurgical system 11 further includes a liquid supply instrument 64 for supplying electrically conducting fluid 50 between electrode terminals 58 and return electrode 10 55. Liquid supply instrument 64 comprises an inner tubular member or return electrode 55 surrounded by an electrically insulating jacket 18. Return electrode 55 defines an inner passage 83 for flow of fluid 50. As shown in FIG. 7, the distal portion of instrument 64 is preferably bent so that 15 liquid 50 is discharged at an angle with respect to instrument 64. This allows the surgical team to position liquid supply instrument 64 adjacent electrode surface 82 with the proximal portion of supply instrument 64 oriented at a similar angle to probe 10.

FIGS. 8 and 9 illustrate another embodiment of probe 10 where the return electrode is an outer tubular member 56 that circumscribes support member 78 and conductors 42. Insulating jacket 18 surrounds tubular member 56 and is spaced from member 56 by a plurality of longitudinal ribs 96 to define an annular gap 54 therebetween (FIG. 9). Annular gap preferably has a width in the range of 0.15 mm to 4 mm. Ribs 96 can be formed on either the jacket 18 or member 56. The distal end of return electrode 56 is a distance L_1 from electrode support surface 82. Distance L, is preferably about 0.5 to 10 mm and more preferably about 1 to 10 mm. The length L₁ of return electrode 56 will generally depend on the electrical conductivity of the irrigant solution

As shown in FIG. 8, electrically conducting liquid 50 flows through annular gap 54 (in electrical communication with the return electrode) and is discharged through the distal end of gap 54. The liquid 50 is then directed ground support member 78 to electrode terminals 58 to provide the current pathway between the electrode terminals and return electrode 56. Since return electrode 56 is proximally recessed with respect to electrode surface \$2, contact between the return electrode 56 and surrounding tissue is minimized. In addition, the distance L, between the active the risk of current shorting therebetween.

The present invention is not limited to an electrode array disposed on a relatively planar surface at the distal tip of probe 10, as described above. Referring to FIGS, 12-14, an alternative probe 10 includes a pair of electrodes 58a, 58b mounted to the distal end of shaft 13. Electrodes 58a, 58b are electrically connected to power supply as described above and preferably have tips 100a, 100b with a screwdriver or flattened shape. The screwdriver shape provides a greater amount of "edges", to electrodes 58a, 58b, to increase the electric field intensity and current density at the edges and thereby improve the cutting ability as well as the ability to limit bleeding from the incised tissue (i.e., hemostasis).

As shown in FIG. 12, current flows between electrode tips 100a and 100b as indicated by current flux lines 60 to heat the target tissue 52. The surgeon then moves probe 10 transversely across tissue 52 to effect an incision 102 in tissue 52, as shown in FIG. 14.

Other modifications and variations can be made to disinvention as defined in the following claims. For example, shaft 13 of probe 10 may have a variety of configurations

other than the generally linear shape shown in FIGS. 1-8. For example, shaft 13 may have a distal portion that is angled, in the range of 10° to 30° (FIG. 10) or 90° (FIGS. 11 and 6), to improve access to the operative site of the tissue 52 being ablated or cut (see FIG. 10). A shaft having a 90° bend angle may be particular useful for accessing gingiva located in the back portion of the patient's mouth and a shaft having a 10° to 30° bend angle may be useful for accessing gingiva near or in the front of the petient's mouth.

In addition, it should be noted that the invention is not limited to an electrode array comprising a plurality of active electrodes. The invention could utilize a phurality of return electrodes, e.g., in a bipolar array or the like. In addition, depending on other conditions, such as the peak-to-peak voltage, electrode diameter, etc., a single active electrode may be sufficient to develop a vapor layer and induce the discharge of energy to ablate or cut tissue, as described

By way of example, FIGS. 21 and 22 illustrate the design of a probe 10 according to the present invention comprising a single active electrode 58 having a tubular geometry. As described above, the return electrode may be an outer tubular member 56 that circumscribes insulated conductor 42 and adhesive bonding material 79 which, in turn, adhesively joins to active electrode support members 48a and 48b. Electrode support members 48a and 48b may be ceramic, glass ceramic or other electrically insulating material which resists carbon or are tracking. A preferred electrode support member material is alumina. In the example embodiment, a solid rod of alumina forms an inner portion 48b of electrode support member 48 and a hollow tube of alumina forms an outer portion 48s of electrode support member 48. Tubular shaped active electrode 58 may be fabricated using shaped cylinder of this metal comprising an electrically conductive metal, such as platinum, tantalum, tungsten, molybdenum, columbium or alloys thereof. Active electrode 58 is connected to connector 19 (see FIG. 2C) via an insulated lead 168. An electrically insulating jacket 18 surrounds tubular member 56 and may be spaced from 40 member 56 by a plurality of longitudinal ribs 96 to define an annular gap 54 therebetween (FIG. 22). Annular gap 54 preferably has a width in the range of 0.15 to 4 mm. Ribs 96 can be formed on either jacket 18 or tubular member 56. The distal end of the return electrode 56 is a distance L, from electrode terminals 58 and the return electrode 56 reduces 45 electrode support surface 82. Distance L₁ is preferably about 0.5 mm to 10 mm and more preferably about 1 to 10 mm. The length L, of return electrode 56 will generally depend on the electrical conductivity of the irrigant solution:

As shown in FIG. 21, electrically conducting liquid 50 flows through annular gap 54 (in electrical communication with return electrode 56) and is discharged through the distal end of gap 54. The liquid 50 is then directed around electrode support member 48a to electrode terminal 58 to provide the current pathway between electrode terminal 58 and return electrode 56. As described above, the active and return electrodes are connected to voltage supply 28 via cable 34 (see FIG. 1).

FIGS. 23 and 24 illustrate further embodiments of electrosurgical probes according to the present invention. In FIG. 23, a probe 10 comprises a multiplicity of electrodes 58 which converge to a single electrode lead 42. As shown, a central electrode 105 extends to the proximal end of the probe shaft for connection to connector 19 (FIG. 2C). The remainder of the electrodes 58 extend through a portion of close embodiments without departing from the subject 65 the probe shaft and are electrically coupled to central electrode 105 by, for example, a weld, solder joint or crimo connection 100. In FIG. 24, an electrosurgical probe 10 comprises a single electrode 58 connected to a single electrode lead 42. As described above, the active and return electrodes are connected to voltage supply 28 via cable 34 (see FIG. 1).

Both of the single active electrode configurations depicted in FIGS. 21-24 may be used with the integral supply means and return electrodes described above in FIGS. 2-11, 30 and 31. Alternatively, these probe configurations may be operated in body cavities already containing an electrically conducting liquid 50, obviating the need for either an integral supply of said liquid or an electrically insulating sleeve to form a conduit for supply of the electrically conducting liquid 50. Instead, an electrically insulating covering would be applied to substantially all of the return electrode 56 (other than the proximal portion).

FIG. 15 illustrates the current flux lines associated with an electric field 120 applied between the active and return electrodes 56, 58 when a voltage is applied therebetween. As shown, the electric field intensity is substantially higher in the region 88 at the tip of the electrode 58 because the current flux lines are concentrated in these regions. This high electric field intensity leads to induced molecular breakdown of the target tissue through molecular dissociation. FIGS. 18-20 illustrate an exemplary embodimanother important application of the present invention in particularly useful for boning a channel through the vaporized electrically conducting liquid 50 in a thin layer 124 between the distal tip 122 of the active electrode 58 and the target tissue 52, as shown in FIG. 16. The vapor layer 124 will usually have a thickness of about 0.02 to 2.0 mm.

As shown in FIG. 16, the electric field ionizes the vapor layer due to the presence of an ionizable species (e.g., sodium) within the vapor layer to create a plasma. This ionization, under optimal conditions, induces the discharge of highly energetic electrons and/or photons from the vapor layer. The photon and/or the energetic electrons cause disintegration of the tissue molecules adjacent to the vapor layer. FIG. 16 illustrates the issuance of bubbles 126 of non-condensible gaseous products resulting from the disintegration of tissue at the target site.

The system and method of the present invention is also useful in dermatological procedures, i.e., surface tissue ablation on the patient's outer skin or epidermis. For example, the probe of the present invention can be used for the removal of tissue abnormalities, pigmentations, such as freckles, tantoos, age or liver spots, birth marks, malignant melanomas, and superficial lentigines in the epidermis, and other unwanted tissue, such as soft fatty tissue, cutaneous angiodysplasia, e.g., skin angloma, malignant tumor tissue, lumbago (i.e., tissue bulges extending from the vertebrae) or the like. In addition, the probe of the present invention may be used for removing surface layers of the epidermis to provide younger looking skin (tissue rejuvenation) or for incising, dividing and resecting tissue during cosmetic surgery procedures.

FIG. 17 illustrates an exemplary embodiment, where an 55 electrosurgical probe 130 is utilized to remove the surface layers of the epidermis 140. Probe 130 includes a shaft 132 coupled to a proximal handle 134 for holding and controlling shaft 132. Similar to previous embodiments, probe 130 includes an active electrode array 136 at the distal tip of 60 shaft 132, an annular return electrode 138 extending through shaft 132 and proximally recessed from the active electrode array 136 and an annular lumen 142 between return electrode 138 and an outer insulating sheath 144. Probe 130 further includes a liquid supply conduit 146 attached to 65 handle 134 and in fluid communication with lumen 142 and a source of electrically conducting fluid (not shown) for

delivering the fluid past return electrode 138 to the target site on the epidermis 140. As discussed above, electrode array 136 is preferably flush with the distal end of shaft 132 or distally extended from the distal end by a small distance (on the order of 0.005 inches) so to minimize the depth of ablation. Preferably, the distal end of shaft 132 is beveled to improve access and control of probe 130 while treating the epidermal tissue.

The voltage will preferably be sufficient to establish high electric field intensities between the active electrode array 136 and the epidermal tissue 140 to thereby induce molecular breakdown or disintegration of several cell layers of the epidermal tissue. As described above, a sufficient voltage will be applied to develop a thin layer of vapor within the electrically conducting fluid and to ionize the vaporized layer or region between the active electrode(s) and the target tissue. Energy in the form of photons and/or energetic electrons are discharged from the vapor layer to ablate the epidermal tissue, thereby minimizing necrosis of surrounding tissue and underlying cell layers, such as cell structures in the stratum hecidium and/or stratum granulosum.

FIGS. 18-20 illustrate an exemplary embodiment of another important application of the present invention. As discussed above, the probe of the present invention may be particularly useful for boting a channel through tissue by axially translating the probe towards the tissue as the tissue is disintegrated by the mechanisms discussed above. In the exemplary embodiment, the probe of the present invention is used in a transmyocardial revascularization procedure to form channels from the myocardium to the ventricular cavity to perfuse the myocardium. This procedure is an alternative to coronary artery bypass surgery for treating coronary artery disease. The channels allow oxygen eariched blood flowing into the ventricular cavity from the acrta to directly flow into the myocardium; rather than exiting the heart and then flowing back into the myocardium through the coronary arteries.

As shown in FIG. 18, electrosurgical probe 10 is positioned into one of the ventricular cavities of the heart, in this case, the right ventricle 200. Electrosurgical probe 10 may be introduced into the right ventricle 200 in a variety of procedures that are well known in the art, such as a thoracotomy, sternotomy or minimally invasive procedures. In the representative embodiment, probe 10 is introduced into the vasculature of the patient through a percutaneous penetration and axially translated via a guide catheter 202 through one of the major vessels to the right ventricular cavity 204. A preferred embodiment incorporates a steerable guide catheter 202 which can be externally controlled by the surgeon to direct the distal portion of the guide catheter 202 and probe 10 to the target site(s) in ventricular cavity 204.

Referring to FIG. 19, ventricle wall 206 comprises an epicardium 208, a myocardium 210 and an endocardium 212. In the representative embodiment, probe 10 will form a channel 214 or artificial vessel from the ventricular cavity 296, through the endocardium 212 and into the myocardium 210 to thereby increase myocardial blood flow from the endocardium 212 to the myocardium 210. The location of channel 214 may be selected based on familiar epicardial anatomic landmarks, such as the epicardial branches of the coronary arteries. Guide catheter 202 is positioned adjacent the inner endocardial wall and probe 10 is axially translated so that the active electrode 58 at its distal end is positioned proximate the heart tissue. In this embodiment, the probe includes a single, annular electrode 58 at its distal tip for ablation of the heart tissue. However, it will be readily recognized that the probe may include an array of electrode terminals as described in detail above.

Electrically conducting liquid 50 is delivered through an annular lumen 220 between an annular return electrode 222 and an insulating sheath 224 of the probe. Return electrode 222 is recessed from the distal end of active electrode 58. preferably about 0.025 to 0.050 inches. Alternatively, the 5 return electrode may be positioned on the exterior surface (skin) of the patient, or it may be located nearby on a more proximal position of the probe. Similar to the above embodiments, a high frequency voltage (e.g., 100 kHz) is applied between active electrode(s) 58 and return electrode 10 222 to establish a current flow therebetween that ablates or disintegrates the heart tissue. The high frequency voltage will preferably be sufficient to vaporize a thin layer of the electrically conducting liquid and to induce the discharge of photon and/or electron energy from the vapor layer to 15 provide cold ablation of the heart tissue.

Ablation of the tissue may be facilitated by axially reciprocating and/or rotating the probe within guide catheter 202 a distance of between about 0.05 to 0.20 inches. This axial reciprocation or rotation allows the electrically con- 20 ducting liquid 50 to flow over the tissue surface being canalized, thereby cooling this tissue and preventing significant thermal damage to the surrounding tissue cells.

FIG. 20 illustrates an alternative embodiment of the probe of FIG. 1. In this embodiment, the probe 260 includes a central lumen 262 having a proximal end attached to a suitable vacuum source (not shown) and an opea distal end 266 for aspirating the target site. The active electrode is preferably a single annular electrode 268 surrounding the open distal end 266 of central lumen 262. Central lumen 262 is utilized to remove the ablation products (e.g., liquids and gases) generated at the target site and excess electrically conductive irrigant during the procedure.

In both of the above embodiments, the present invention 35 provides localized ablation or disintegration of heart tissue to form a revascularization channel 214 of controlled diameter and depth. Usually, the diameter will be in the range of 0.5 mm to 3 mm. Preferably, the radio frequency voltage will be in the range of 400 to 1400 volts peak-to-peak to provide controlled rates of tissue ablation and hemostasis while minimizing the depth of accrosis of tissue surrounding the desired channel. This voltage will typically be applied continuously throughout the procedure until the desired length of the channel 214 is completely formed. However, 45 the heartbeat may be monitored and the voltage applied in pulses that are suitably timed with the contractions (systole)

It should be noted that the above embodiment is merely representative and is not intended to limit the invention. For 50 example, the electrosurgical probe can be used to effect a myocardial revascularization channel from the exterior of the heart into the ventricular cavity. In this procedure, the probe will be introduced into the thoracic cavity and posiwalls via one of a variety of conventional manners. The above electrosurgical procedure will then be performed as the electrode is translated towards the heart until a channel is formed to the ventricular cavity.

The system and method of the present invention may also 60 be useful to efficaciously ablate (i.e., disintegrate) cancer cells and tissue containing cancer cells, such as cancer on the surface of the epidermis, eye, colon, bladder, cervix, uterus and the like. The present invention's ability to completely disintegrate the target tissue can be advantageous in this 65 application because simply vaporizing cancerous tissue may lead to spreading of viable cancer cells (i.e., seeding) to

other portions of the patient's body or to the surgical team in close proximity to the target tissue. In addition, the cancerous tissue can be removed to a precise depth while minimizing accrosis of the underlying tissue.

What is claimed is:

1. A method for applying energy to a target site on a patient body structure comprising:

providing an electrode terminal and a return electrode electrically coupled to a high frequency voltage source; positioning the active electrode in close proximity to the target site in the presence of an electrically conducting terminal: and

applying a high frequency voltage between the electrode terminal and the return electrode, the high frequency voltage being sufficient to vaporize the fluid in a thin layer over at least a portion of the electrode terminal and to induce the discharge of energy to the target site in contact with the vapor layer.

2. The method of claim I wherein the electrode terminal comprises an electrode array including a plurality of isolated

electrode terminals.

3. The method of claim 2 wherein the isolated electrode terminals each have a contact surface area in the range of about 0.25 mm² to 50.0 mm².

4. The method of claim 2 wherein the isolated electrode terminals have circular contact surfaces with an area in the range from 0.01 mm² to 1 mm².

5. The method of claim 2 wherein the electrode terminals are spaced from each other a distance of about 0.0005 to 2.0

6. The method of claim 2 wherein the electrode array is disposed over a distal tip of an electrosurgical probe.

7. The method of claim 2 wherein the electrode terminals comprises a material with a relatively low thermal conductivity.

8. The method of claim 7 wherein the electrode materials comprises a material selected from the group consisting of titanium, tungsten, platinum, alumiaum and tantalum.

9. The method of claim 2 wherein the return electrode has distal end positioned proximal to the electrode array.

10. The method of claim 2 wherein the electrode height of the most distal portion of any of the electrode terminals relative to the most proximal portion of said electrode terminals exposed to the electrically conducting fluid is in the range from 0.0 to 2.0 mm.

11. The method of claim 2 wherein the electrode terminals are surrounded and supported by an insulating matrix at or near the distal tip of the probe to electrically isolate proximal portions of the electrode terminals from the electrically conductive fluid, the insulating matrix comprising an inorganic material.

12. The method of claim 11 wherein the inorganic material is selected from the group consisting essentially of ceramic, glass and glass/ceramic compositions.

13. The method of claim I wherein at least a portion of the tioned adjacent the epicardial layer of one of the ventricular 55 energy induced is in the form of photons having a wavelength in the ultraviolet spectrum.

14. The method of claim I wherein at least a portion of the energy is in the form of energetic electrons.

15. The method of claim 14 wherein the energy of the energetic electrons is sufficient to cause disassociation or disintegration of molecules of the body structure.

16. The method of claim 14 wherein the energy evolved by the energetic electrons is greater than 3 eV.

17. The method of claim I wherein the high frequency roltage is at least 200 volts peak to peak.

18. The method of claim I wherein the voltage is in the range from 500 to 1400 volts peak to peak.

19. The method of claim 1 wherein the electrode terminal is positioned between 0.02 to 5 mm from the target site.

20. The method of claim 1 wherein the vapor layer has a thickness of about 0.02 to 2.0 mm.

21. The method of claim 1 wherein the distance between 5 the most proximal portion of the electrode terminal and the most distal portion of the return electrode is in the range from 0.5 to 10 mm.

22. The method of claim 1 wherein the electrode terminal and the return electrode are of comparable size and comprise 10 a bipolar array of isolated electrode terminals which both come in close proximity or in contact with the body structure.

23. The method of claim 1 wherein the liquid phase of the electrically conducting fluid has a conductivity greater than 15 2 mS/cm.

24. The method of claim 1 wherein the liquid phase of the electrically conductive fluid comprises isotonic saline.

25. The method of claim 1 wherein the electrode height of the most distal portion of the electrode terminal relative to 20 the most proximal portion of the electrode terminal exposed to the electrically conducting fluid is in the range from 0.0 to 2.0 mm.

26. A method for applying energy to a target site on a patient body structure comprising:

providing an active electrode and a return electrode electrically coupled to a high frequency voltage source;

positioning the electrode terminal in close proximity to the target site in the presence of an electrically conducting fluid; and

applying a high frequency voltage between the electrode terminal and the return electrode, the high frequency voltage being in the range from 500 to 1400 volts peak to peak.

27. The method of claim 26 wherein the high frequency voltage is in the range from 700 to 900 volts peak to peak 28. A method for applying energy to a target site on a patient body structure comprising:

providing an electrode terminal and a return electrode electrically coupled to a high frequency voltage source; positioning the electrode terminal in close proximity to the target site in the presence of an electrically conducting fluid; and

applying a high frequency voltage between the electrode 45 terminal and the return electrode, the high frequency voltage being sufficient to impart sufficient energy into the target site to ablate the body structure without causing substantial tissue necrosis below the surface of the body structure underlying the ablated body structure.

29. The method of claim 28 wherein the applying step comprises:

vaporizing the electrically conducting fluid in a thin layer over at least a portion of the electrode terminal; and inducing the discharge of photons to the target site in contact with the vapor layer.

30. The method of claim 28 wherein the applying step comprises:

vaporizing the electrically conducting fluid in a thin layer over at least a portion of the active electrode surface; and

inducing the discharge of energetic electrons to the target site in contact with the vapor layer.

31. The method of claim 28 wherein the depth of necrosis is 0 to 400 microns.

32. A method for applying energy to a target site on a patient body structure comprising:

providing an active electrode electrically coupled to a high frequency voltage source;

positioning the electrode terminal in close proximity to the target site in the presence of an electrically conducting fluid; and

generating a voltage gradient between the electrode terminal and tissue at the target site, the voltage gradient being sufficient to create an electric field that cause the breakdown of tissue through molecular dissociation or disintegration.

33. The method of claim 32 wherein the generating step comprises:

providing a return electrode electrically coupled to a high frequency voltage source;

applying a high frequency voltage between the electrode terminal and the return electrode; and

vaporizing the electrically conducting fluid in a thin layer over at least a portion of the electrode terminal.

34. The method of claim 33 further comprising developing a film layer of vapor between the active electrode and the body structure at the target site.

35. The method of claim 33 further comprising cooling the tissue with the electrically conducting fluid to reduce the temperature rise of those portions of the body structure adjacent the target site.

36. The method of claim 35 wherein the cooling step includes translating the distal surface of the electrode terminal over the target site to allow the electrically conducting fluid to contact the tissue after the tissue has been subjected to the electric field.

37. The method of claims 1 and 28 wherein the electrode terminal is surrounded and supported by an insulating matrix at or near the distal tip of the probe to electrically isolate the proximal portion of the electrode terminal from the electrically conductive fluid, the insulating matrix comprising an inorganic material.

then body structure comprising:

38. The method of claim 37 wherein the inorganic mateproviding an electrode terminal and a return electrode
electrically coupled to a high frequency voltage source;
electrically coupled to a high frequency voltage source;

39. The method of claim 37 wherein the distal surface of the electrode terminal is recessed below the surface of the insulating matrix by a distance from 0.01 mm to 1.0 mm.

40. The method of claim 37 wherein the distal surface of the electrode terminal is flush with the surface of the insulating matrix.

41. The method of claims 28 and 32 wherein the electrode terminal comprises an electrode array including a plurality of isolated electrode terminals.

42. The method of claim 41 wherein the generating step comprises:

providing a return electrode electrically coupled to a higher frequency voltage source;

applying a high frequency voltage between the return electrode and the array of electrode terminals; and

vaporizing the electrically conducting fluid in a thin layer over one or more of the electrode terminals of the array.

43. The method of claim 42 further comprising develop-60 ing a film layer of vapor between one or more of the electrode terminals and the target site.

44. The method of claim 42 further comprising cooling the tissue with the electrically conducting fluid to reduce the temperature rise of those portions of the body structure 65 adjacent the target site.

45. The method of claims 1 and 33 wherein the density of the vapor layer is less than about 10²⁰ atoms/cm³.

46. The method of claims 1 and 30 wherein the electrode terminal is configured to promote bubble nucleation causing the formation of the vapor layer.

47. The method of claims 1 and 28 wherein the electrode terminal has a contact surface area in the range of about 0.25 5

 mm^2 to 50 mm^2 .

48. The method of claims 26 and 28 wherein the high frequency voltage is at least 200 volts peak to peak.

49. The method of claims 26 and 28 wherein the high volts peak to peak.

50. The method of claims 26 and 28 wherein the electrode terminal is positioned between 0.02 to 2.0 mm from the

target site.

51. The method of claims 26 and 28 wherein the electrode 15 terminal and the return electrodes comprise a bipolar array of isolated electrode terminals.

52. The method of claims 1 and 28 further comprising cooling the tissue with the electrically conducting fluid to reduce the temperature rise of those portions of the body structure adjacent the target site.

- 53. The method of claim 52 wherein the cooling step includes translating the distal surface of the active electrode over the target site to allow the electrically conducting fluid to contact the tissue after the tissue has been subjected to the electric field.
- 54. The method of claims 1 and 28 further comprising frequency voltage is in the range from about 500 to 1400 10 evacuating fluid generated at the target site with a suction lumen having a distal end adjacent the electrode terminal.
 - 55. The method of claims 1 and 28 wherein the target site is a tumor within or on the patient's body.
 - 56. The method of claims 26 and 28 wherein the electrode terminal comprises an electrode array including a plurality of isolated electrode terminals.

UNITED STATES PATENT AND TRADEMARK OFFICE CERTIFICATE OF CORRECTION

PATENT NO. : 5,697,882

DATED

December 16, 1997

INVENTOR(S):

Philip E. Eggers, et. al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

IN THE CLAIMS:

23. A method for applying energy to a target site on a patient body structure comprising:

providing an electrode terminal and a return electrode electrically coupled to a high frequency voltage source;

positioning the [active] electrode terminal in close proximity to the target site in the presence of an electrically conducting [terminal] fluid; and

applying a high frequency voltage between the electrode terminal and the return electrode, the high frequency voltage being sufficient to vaporize the fluid in a thin layer over at least a portion of the electrode terminal and to induce the discharge of energy to the target site in contact with the vapor layer.

Signed and Sealed this

Seventh Day of April, 1998

Attest:

BRUCE LEHMAN

Dence Cedorar

Assessing Officer

Commissioner of Patents and Trademarks

ATENT AND TRADEMARK OFFICE CERTIFICATE OF CORRECTION

PATENT

: 5,697,882

DATED

: December 16, 1997

INVENTOR(S): Philip E. Eggers et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 24, lines 6-18, claim 1, should read as follows:

1. A method for applying energy to a target site on a patient body structure comprising:

providing an electrode terminal and a return electrode electrically coupled to a high frequency voltage source;

positioning the electrodé terminal in close proximity to the target site in the presence of an electrically conducting fluid; and

applying a high frequency voltage between the electrode terminal and the return electrode, the high frequency voltage being sufficient to vaporize the fluid in a thin layer over at least a portion of the electrode terminal and to induce the discharge of energy to the target site in contact with the vapor layer.

This certificate supersedes Certificate of Correction issued April 7, 1998.

Signed and Sealed this

Twenty-fifth Day of August, 1998

Since Tehran

Attest:

BRUCE LEHMAN

Attesting Offices

Commissioner of Potents and Trademarks

UNITED STATES PATENT AND TRADEMARK OFFICE CERTIFICATE OF CORRECTION

PATENT NO. : 5,697,882

Page 1 of 2

DATED

: December 16, 1997

INVENTOR(S):

Philip E. Eggers et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

IN THE CLAIMS:

37. The method of claims 23 or 48 wherein the electrode terminal is surrounded and supported by an insulating matrix at or near the distal tip of the probe to electrically isolate the proximal portion of the electrode terminal from the electrically conductive fluid, the insulating matrix comprising an inorganic material.

- 45. The method of claims 23 or 55 wherein the density of the vapor layer is less than about 10²⁰ atoms/cm³.
- 46. The method of claims 23 or 50 wherein the electrode terminal is configured to promote bubble nucleation causing the formation of the vapor layer.
- 47. The method of claims 23 or 48 wherein the electrode terminal has a contact surface area in the range of about 0.25 mm² to 50 mm².
- 48. The method of claims 48 or 52 wherein the high frequency voltage is at least 200 volts peak to peak.
- 49. The method of claims 48 or 52 wherein the high frequency voltage is in the range from about 500 to 1400 volts peak to peak.
- 50. The method of claims 48 or 52 wherein the electrode terminal is positioned between 0.02 to 2.0 mm from the target site.
- 51. The method of claims 48 or 52 wherein the electrode terminal and the return electrodes comprise a bipolar array of isolated electrode terminals.

UNITED STATES PATENT AND TRADEMARK OFFICE CERTIFICATE OF CORRECTION



PATENT NO. :

5,697,882

Page 2 of 2

DATED

: December 16, 1997

INVENTOR(S): Philip E. Eggers et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

- 52. The method of claims 23 or 48 further comprising cooling the tissue with the electrically conducting fluid to reduce the temperature rise of those portions of the body structure adjacent the target
- 54. The method of claims 23 or 48 further comprising evacuating fluid generated at the target site with a suction lumen having a distal end adjacent the electrode terminal.
- 55. The method of claims 23 or 48 wherein the target site is a tumor within or on the patient's body.
- 56. The method of claims 48 or 52 wherein the electrode terminal comprises an electrode array including a plurality of isolated electrode terminals.

Signed and Sealed this Second Day of May, 2000

Attest:

Q. TODD DICKINSON

Attesting Officer

Director of Patents and Trademarks

United States Patent im

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. Sep. 26, 1978

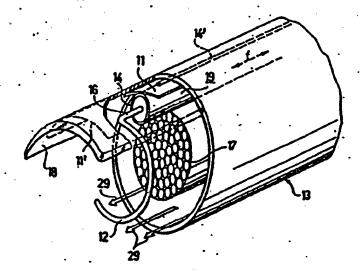
Roos	
[34] PLECIR	- SURGICAL DEVICE
[75] Investor:	Eberhard Roos, Turtlingen, Fed. Rep. of Germany
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[21] Appl No.	: 686,600
	May 14, 1976
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May 15; 1975 [DE) Fed Rep. of Generally 2521719
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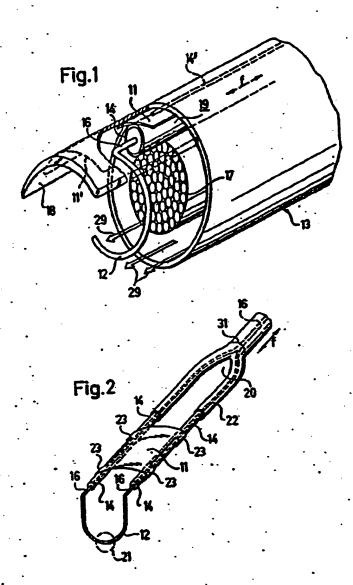
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Electro-surgical device with an insulated cable wi Electro-surgical device with an invalsted cable which can be passed through an endoscope, to which can be connected the pole of a high frequency generator, said pole being invalsted from earth potential and on whose end facing the body cavity is provided a small-seen treatment electrode projecting from the endoscope, said treatment electrode cooperating with a large-area neutral electrode connected to the other pole of the high frequency generators which is immisted from earth potential in such a way that due to the high correct dessition frequency generator by meant of an insulated which can also be passed through the endoscope

20 Claims, 9 Draving Pip



DEFENDANT'S EXHIBIT

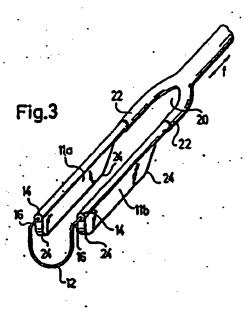


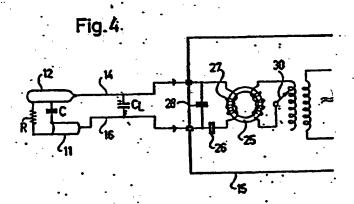
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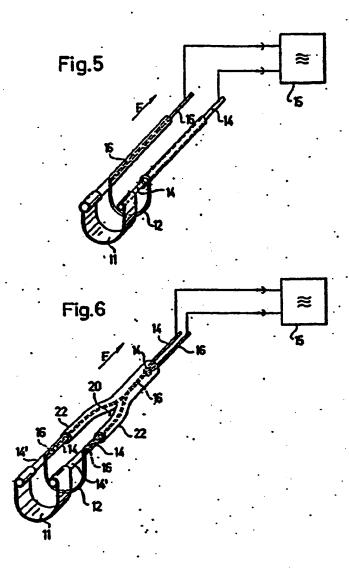
U.S. Patent Sept. 26, 1978

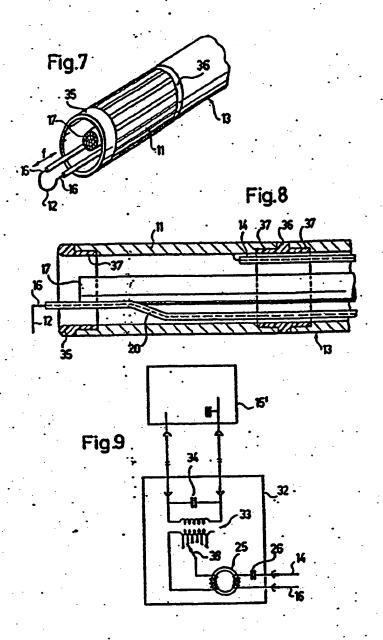
Sheet 2 of 4

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ELECTRO - SURGICAL DEVICE

BACKGROUND OF THE INVENTION

The invention relates to an electro-surgical device-5 with an insulated cable which can be passed through an enforceps, to which can be connected the pole of a high frequency generator, said pole being immisted from earth potential and on whose end facing the body cavity is provided a imall-area treatment electrode pro- 10 jecting from the endoscope, said treatment electrods cooperating with a large-area acutral electrode connected to the other pole of the high frequency generator which is insulated from earth potential in such a way that due to the high current density in the area of the 15 by the measures in question. treatment electrode, a generation of heat takes place which is adequate for separating or congulating tisese.

Electro-surgical devices of this type permit electro-surgical operations of the filled bladder (electro-resotion, e.g. of bladder temors and the prostate glands) 20 using endoscopes, particularly resectoscopes and cysto-

The high degree of development in the endoscope field has resulted in operations in the bladder and on the prostate glands ming these instruments and by means of 25 electro-surgery have become the most commonly used operating procedure.

In known devices of this type, high frequency alter-nating current is fed via an earthed neutral electrode on the one hand and via a sparking ball or cutting loop well explained relative to the outer shaft of the endoscope on the other to the operating area for congulation purposes in the case of hemorrhages. Due to the relatively small area of the cutting loop compared to the area of the pentral electrode applied externally to the patient's 15 body a very high current density occurs in the area of the cutting loop which results in heat generation in the tissue linked with the bursting of the tissue cells thro steam generation and consequently a separation of the tissues. For the desired enting or congulating effects, the moceaner where when a continuous statements the accessary power values of the high frequency cur-rent applied vary between 120 and 130 W.

As the leads from the high frequency generator to the cutting electrods have to be passed through the metallic endoscope, the distances between the high frequency-carrying lead and the remaining metal parts of the endoscope insulated therefrom are so small that especiances of considerable size calst between these metal parts. Thus, to a certain extent, the endoscope forms a capacitor via which part of the applied capacity flows away as 30 leakage current onto the tissue engaging with the metal endoscope shalt. A further, still larger portion of the applied capacity flows from the cutting loop via the washing water directly to the metal parts of the endo-scope shaft located in the washing water flow and from there to the engaging tissue. Thus, uncontrollable elec-trical conditions in the wrethrid tissue engaging with the endoscope and the unequal distribution of lubricasts with invaluding properties on the endoscope shaft can cause critical current dendition when the leakage current

passes to the surthus and this results in burns.

These difficulties would not be eliminated by coating
the endoscope shall with tabes of high grade insulating mbdeg meterial, because the slightest damage to the shift inc materiat, occasion are augment unimity to the main and hities does to the very high current densities occur dure to ing the passage of the leakage current would, in fact, increase the danger of burning due to the damage. How-ever, if the endoscope shaft insulation remains intact,

11.1

the entire leakage current is led off to the points where the operator is in contact with the endoscope leading to burns to the operator's face or to the eye in contact with the metal excutcheous of the transparent optics.

Neutral electrode holation from earth potential cannot prevent the passage of the leakage currents to the operator. As the sentral electrode acts as an opposite pole to the cutting or congulation electrode between the patient and the earthed operating table, it is capacitively connected to earth potential. Therefore, the cutting loop and the leakage current flown therefrom together with its voltage are earthed. Since, in any case, the operator largely carries the earth potential, the passage of the leakage current to the operator cannot be avoided

BRIEF SUMMARY OF THE INVENTION

The problem of the invention is therefore to provide as electro-surgical device of the type indicated hereis-before where underied burns to the unrules and the operator are effectively avoided.

According to the invention, this problem is solved in that the large-area neutral electrode is arranged in the vicinity of the trestment electrode and is connected with the other pole of the high frequency generator by means of an invalued cable which can also be pessed through the endoscope. In this way, potential co action takes place in a spetially very necessity defined zone. Both the treatment electrode, preferably constructed as a cattleg loop and the neutral electrode carry no potential to earth. Lenkage carrent does not flow to the endoscope shaft either from the high frequency lend to the triatment electrode or from the lend to the neutral electrode. Due to the existing cap trace, leakage currents only flow between the leads, but these do not have any external effects.

However, due to the small-area construction of the treatment electrode, a high current density is obtained there, which is adequate for tissue arganetics or coagulation, whereas the acsural electrode arranged in the immediate vicinity has such a large area that underived heating is avoided there.

According to a preferred embodiment, the two feed leads comprise a coaxial cable, whose shield forms one conductor and is lumined relative to the endoscope. Thus, the two high frequency leads for the treatment and neutral electrode form a structural unit, which whilst taking up only a small amount of space, can be simply passed through the endoscope together with the optical and washing portions.

In general, the treatment electrode should be in loop form so that the operator's field of vision is uninter-

According to a further embodiment, the centre conductor of the cosmist cubic at the front projects above the shield and at this point passes into the treshment electrode. It is thereby particularly advantageous if the shield is constructed as a rigid sleeve and in such a way that the treatment electrode can be moved backward and forwards relative to the endoscope via the coaxial cable. Thus, in this embodiment, the coaxial cable at the same time forms the support and operating member for the treatment electro

The relatively large nestral electrode is iniversia geomity directly fixed to the coaxial cable shield. In this way the accural electrode can be mounted reliably sad ovably is an inexpensive and uncomplicated m

Advantageously, the neutral electrode is constructed as an elongated metal sheet slightly corved about the endoscope shaft and extending on either side over the consid cable.

According to a further advantageous emb the endoscope has a plastic extension extending over a amail portion only of its periphery, whereby the treatment electrode can be moved backwards and forwards beneath the said extension. This plastic extension has the advantage that the washing liquid can be satisfactorily guided and those which is not to be treated can be kept away from the treatment electrode. According to the invention, this extension can be used so that the large-area scutral electrode is fixed in insulated manner relative to the endoscope on the inside of the extension. IS The pestral electrode in then preferably connected with The neutral electrode in then preserve connected when the high frequency generator by an invalued cable secured in the endoscope. In this case, only the other conductor with its insulation and treatment electrode is confuctor with its insulation and treatment electrode is the accompanying drawings conductor with its insulation and treatment electrode is to which, by way of illustration show presented embodiments. azially movable.

According to a particularly preferred embodi the coaxial cable has a bifurcation just before the body side end of the endescope and the two laner conductors emissing from the bifurcation are interconnected by a loop forming the treatment electrode. This construct is particularly stable due to the symmetry conditions resulting from the bifurcation, whereby at the same time the operator still has good visibility through the cutting

loop forming the treatment electrode.

If the treatment electrode is used for coagulation purposes, a coagulation sparking ball is firred to the treatment electrode.

The coaxial cable is advantageously surrounded by an invaluing lead so as to prevent any connection of the endoscope metal with the high frequency voltage. Preferably, the insoluting siceve of the bifurcated coatial cable is also bifurcated, but it extends only to just in front of the neutral electrode.

In the case of the biforcated coaxial cable, the neutral electrode is preferably an eleogated metal sheet, beat d the endoscope shaft and extending from aliebily arou one branch of the bifurcation to the other. The sheet can have projections at the four corners which are placed around the shields. Depending on the degree of 45 placing around and also clamping, any desired fixing of the neutral electrode to the coaxial cable can be ob-

The current density in the area of the operating a is advantageously influenced if the neutral electrode 30 terminates at a distance from the end of the shield.

According to a further advantageous embodimes the neutral electrode comprises two pertial electrodes extending in the direction of the loop away from the two arms of the bifurcation. Preferably, the partial elec-trodes do not extend quite as far from the shields as the loop. At the front and year ends the sheets preferably have rounded portions.

As a result of the slide-like construction, the operator can reliably raids the endoscope by placing the slide- 60 like sheet projections on the tissue to then be removed. As is known, the endoscope is operated in such a way that the cutting loop is moved forwards relative to th endoscope, made live and then slowly retracted whereby the times is removed by the heating on the 65 and L

cutting loop.

As stated hereinbefore, the treatment electrode and neutral electrode are appropriately so shaped and posipioned that the Elumination, vision and washing operations are not impaired by the endoscope.

Advantageously, the leads are inductively connected Advantageously, the leads are insectively advanta-to the high frequency generator, whereby advanta-geously, a expection for filtring out low frequency voltage portions is preferably provided in one lead. This, in advantageous manner avoids faradic effects in

the muscular system of the patient.

A capacitor is appropriately connected in parallel to the output winding of the transmitter which with th inductor of the latter forms as oscillating circuit which is tuned in such a way that the attenuation in the oscil-lating circuit formed by the leads, treatment electrode and neutral electrode is minimal.

BRIEF DESCRIPTION OF THE DRAWINGS

ments of the present investion and the principles thereof and what are now considered to be the best modes contemplated for applying these principles.

Other embodiments of the invasion embodying the same or equivalent principles may be used and structural changes may be made if desired by those stilled in the art without departing from the invention and the scope of the appended claims. In the drawings shows

FIG. 1 a schematic, greatly enlarged perspective view of the front end of an endoscope equipped with the electro-surgical device according to the investion.
FIG. 2 a perspective view of a further embodiment of

the electro-surgical device according to the invention, without the endoscope surrounding the same.

FIG. 3 a further embodiment of the cicetro-s device according to the invention, once again without a ding radoscope.

FIG. 4 a schematic circuit diagram of the electro-earpical device according to the invention with a particu-

hely suitable high frequency generator.

FIGS. 3 and 6 perspective views of two further ad-

vanageous emonuments

FIGS. 7 and 8 a pumperaise view and an axial section
of a further advantageous embodiment.

FIG. 9 a schematic circuit diagram of an additional
device for the device according to the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

According to FIG. 2, as endoscope 13 is axial traversed in conventional manner by a fibre optical system 17, which is special relative to the sides of the endoscope 13, in such a way that washing liquid can past through there (arrow 27) and there still remains at for the axial insertion of an electro-surgical treats

According to the invention, this electro-enrgical treatment device comprises a coaxial cable 19 with rigid actuallic shield 14 and an inner conductor 16 axially Inserted together with the fibre optical system 17. Inside the metallic shaft of the endoscope 13, the thicld 14 is covered in not shown manner with an insulating shows 22, shows in the case of the constructions of FIGS. 2

At the front, inner conductor 16 projects somewhat from the counial cable 19 and passes into the trestment electrode 12, which is general comprises a loop ene

ing free visibility for the operator via the fibre optical

The opposite electrode for the cutting electrode 12 in formed by a sentral electrode 11 fixed in electrically conductive manner to shield 14 and which is curved somewhat about the endoscope shaft, having a rectangular, elongated form shown in FIG. 1. Inner conductor 16 and shield 14 are connected, as shown in FIG. 4 to the two poles of a high frequency generator 15 which are not at earth potential.

At the front end of the metal shaft of the endoscope 13 is fixed a plastic extension 18, which is rounded and extends in the manner shows in FIG. 1, 30 as not to impair insertion, for example into the urethrn. As the plastic extension 18 is an insulating body, the large-area neutral electrode 11' can also be fitted to the intithen appropriately connected with the associated pole of the high frequency generator via a separate insulated conductor 16 in the endoscope, inside of via the shield

As a result of the comtraction according to the invention, a high frequency field is only formed between shield 14 and inner conductor 14, as well as between neutral electrode 11 and treatment electrode 12, as is own schemetically in FIG. 4 by especiaces Cg and C. Des to the current conduction through the tissee fluid and tissue itself, a true resistor R is also conceivable parallel to the capacitor between neutral electrode 12 and treatment electrode 12.

The supply to connect neutral electrode 11 and the treatment electrode 13 takes place by the inductive coupling of a high frequency voltage by means of a transformer 25, whose input voltage is regulatible by a variable top 30. Due to the inductive coupling, the output lims H and 16 are galvanically holated from earth ng, the out- 35 potential.

A capacitor 26 connected in lead 16 is used for filter ing out the low frequency current and therefore avoids feradic effects in the muscular system of the patient. A t vinding capacitor 28 connected in parallel to the outp 37 of transformer-25 and behind capacitor 26 forms with the output winding an oscillating circuit tuned in such a wey that the attenuation in the oscillating circuit formed from C₂, C and R as well as the inductors of as lines 14, 16 is minimal.

As a result of the construction according to the is vention, the leakage currents only flow between fines 14, 16 and therefore do not reach the metal shaft of endoscope 13. Thus, larger current densities such as are 30 necessary for times separation or congulation only neces outside the endoscope in the operating area.

Therefore, the danger of heating outside the desired

ra, M well as burns to the operator is reliably avoided. FIG. 2 shows a particularly advantageous embodi- 25 ment of the electro-surgical device according to the invention in which both the inner conductor 16 and the shield 14 have a bifurcation 29. I, the same way, the invaliding slowe drawn over the shield 14 is bifurcated. The production of such a bifurcation is advantageously 40 obtained by a welded joint at point 31 indicated by a

As a result of the bifurcation shows in FIG. 2, a cutting loop 12 can be arranged in the shown manner between the two inner conductors 16 eminating at the 43 end. If the treatment electrode is to be med for coagu tion, a coagulation sparking ball 22 can be provided on

The construction of FIG. 2 is particularly well suited to the arrangement of a relati vely large-area acuttal electrode 11 which appropriately extends between the shields 14 of the two branches of the bifurcation 20, being slightly bent about the endoscope shaft. At the end, the neutral electrode 11 has projections 23 which are securely placed around the shields 14 for securing neutral electrodes 11 and for supplying the same with voltage. The metal sheeting forming the neutral electrode simultaneously constructionally semiorous the bifurcation 20, so that the guidance of the treatment electrode 12 by the operator is aided. As is known, the axial movement of the electro-surgical device in the direction of the double arrow / takes place by operating a pistol-like handle on endoscope 13, not shown in the drawing.

A further advantageous embodiment is shown in FIG. 3 where the neutral electrode is broken up into two partial electrodes 214, 11A, which in the represented manner are soldered or welded to the shields 14 in such a way that the partial electrodes extend in th same direction as estring loop 12. Rounded portions 24 are provided at both ends. The partial electrodes 11s. 11s applied to the shields 14 in this way thus addition-25 ally form slide-like support, by means of which the electro-surgical device can be placed on the tissue to be removed. This not only exsures a reliable guidance of the device but sho ensures that the tissue is removed to the predetermined depth. The electrical advantages of limiting current conduction to the operating area are

completely maintained.

FIG. 5 shows a further advantageous embodi whereby only the front part of the electro-surgical device without the endoscope is shown. In this embodi ment, two inmisted cables with inner conductors 14, 26 are passed from high frequency generator 15 through the endoscope. At the front end are successively asutting loop 12 and the neutral electrode 21 constructed as a steel band. The custing loop 12 is electrically conductively connected with the inner conductricing connectively connective wan are more convenience in 16, but at the other end is only fixed to the insulation surrounding the conductor 16. Convenient, the steel band 11, whose shape is similar to the cutting loop 12, is connected in electrically conductive and mechanically secure maner with the inner conductor 14, whilst the opposite rad is mechanically secured to the invalsation of the inner conductor 16. Since, according to the invention, the steel band 11 has the same radius as the wise loop, on retracting the loop 12 in the direction of arrow P, the bead does not form an obstacle to the tissue portions removed by the loop. The neutral electrode 11 in the form of the steel band rests on the tissue in largeares form, so that good electrical contact is ensure

FIG. (shows an embodiment which is substantially the same as FIG. 5, whereby however, a bifurcated coarial cable, similar to FIGS. 2 and 3 is used. The wire loop 12 is once again fixed to the inner conductors 16, whilst the acestral conductor 11 in band form is mechanically accured to extensions 14' electrically connected

with the ableld 14.

In the embodiment according to PIGS. 7 and 8, the front portion of endoscope 13 kself or a control connection attached thereto at the frost is constructed as the neutral electrode 11. To this end, the frost portion is electrically insulated relative to the rear portion or the front-litted connection from endoscope 13 by an in mediately inserted insulating ring 36. The cutting i 12 can at the front be passed out of the acutral electron

11 in one of the above-described manners. In the present embodiment, two leads 16 pass outwards from the cylindrical neutral electrode 11, which at 20 are combined to form a single cable, leading to the rear end of endoscope 13. The neutral electrode 11 is connected vin a 5 further insulated cable 14 to the high frequency generator 15 not shown in FIGS. 7 and &

It is also important in the case of the embodiments of FIGS. 7 and 8 that the cutting loop extends radially up to an insulating ring 35 mounted at the front on the 10 neutral electrode 11 and can be retracted up to this. In this way, the front edge of the endoscope shaft, namely the front edge of the insulating ring 35 serves as a se port for the cutting loop 12, so that the material is reliably removed therefrom. Therefore, as shown the insulating ring 35 must be rounded at the frost.

Preferably, the insulating tings 35, 36 have axial atnehments 37 with a reduced external diameter, by means of which a mechanically secure fixing to the metal tubes is carured.

FIG. 9 shows an additional device 32, by means of which a conventional high frequency surgical apparatus 15' with an earthed output terminal can be made usable for the purposes of the invention. The additional device 32 connected to the high frequency apparatus 15" has at 23 the inlet a transformer 33 with parallel-connected capaction 34 for making to the rescount frequency of the output circuit of the high frequency apparatus 15°. The output winding of transformer 33 is preferably regulatable by means of a loop arm 38 in such a way that the 30 inductive output transformer 25 can receive voltages of varying sizes.

Via a capacitor 24, the output winding of transformer The applied to the two output terminals of the additional device 32, where the leads 14, 16 can be applied. 35 in this way the high frequency apparatus 15' acquires an output with factuating potential, as is necessary for

section of the electro-surgical device according

The investion is not limited to the embodiments de- 40 acribed and represented hereinbefore and various modifications can be made thereto without passing beyond the scope of the investion.

What is claimed in: 1. In combination: an endoscope having an endoscope body of substantially tubular shape, and an electro-sur-gical device comprising a treatment electrode projecting at one end from said endoscope body and a neutral electrode arranged adjacent said treatment electrode, involuted cable means for connecting said treatment electrode to one pole of a high-frequency generator, ed means for ex secting said neutral electrode to th and means for connecting said neutral electrode to the other pole of a high-frequency generator, said endo-scope body having an-insulating projection extending over a portion of the peripheny of said endoscope body 33 at said one end and having a front edge, said neutral electrode being located within said endoscope body and spaced a distinct distance inwardly from said front edge, a space being formed between said treatment electrode and said sentral electrode which is adapted to 40 be filled with liquid to provide electrical conductance between said electrodes

2 The combination of claim 1, wherein said insulated cable means and said means for connecting said neutral electrode to said other pole comprise coasial cable 65 means with shirlding means forming one of said con-accting means and being invalated relative to said endoscope body.

3. The combination according to claim 2, wherein said shielding means is constructed as a rigid alceve in which said treatment electrode is adapted to be moved back and forth relative to mid endoscope body through said coaxial cable means.

4. The combination according to claim 2, wherein said sestral electrode is fixed directly to said shielding means of said coasial cable means

5. The combination according to claim 4, wherein the acutral electrode is constructed as an elongated metal sheet slightly beat within said endoscope body and extending over said coaxial cable meass.

6. The combination according to claim 2, comprising an inculating sleeve surrounding said coaxial cable

7. The combination according to claim 6, wherein said insulating sleeve is hisurcated and extends approximately to said neutral electrode.

2. The combination according to claim 7, wherein said neutral electrode in an elongated metal abeet slightly bent within said endoscope body and extending from one branch of said bifurcated insulating sleeve to the other.

9. The combination according to claim 8, wherein mid sheet has projections at its four conners, two each of which are placed around the respective branches of said bifurcated sleave.

10. The combination according to claim 2, wherein said neutral electrode terminates at a distance from said shielding means.

11. The combination according to claim 1, wherein said neutral electrode is secured to and insulated from said endoscope body on the inside of said insulating

12. The combination according to claim 1, wherein said means for connecting said neutral electrode to said high-frequency generator is an insulated conductor recured in said endoscope body.

13. The combination according to claim 2, wherein said coaxial cable means has a bifurcation at that end of the andescope body adjacent said projection, two inner conductors emissing from said bifurcation, and a loop terconnecting said two laner conductors and form said treatment electrode.

14. The combination according to claim 1, wherein a congulation sparing ball is fitted to said treatment elec-

15. The combination according to claim 1, comprising a high-frequency generator, and wherein said cable means and said connecting means are inductively conpled to said high-frequency generator.

16. The combination according to claim 15, wherein a capacitor is connected in one of said cable means and said connecting means for filtering out low-frequency vokage,

17. The combination according to claim 15, whe said generator comprises a transformer with an output winding having an inductor, a capacitor being con-acted parallel to said output winding and forming an oscillating circuit with said inductor, said circuit being bred such that the attenuation in said circuit formed by said cable meant, said connecting means, treatment electrode and neutral electrode is minin

12. The combination according to claim 15, comprising means for potential bolation connected between said high-frequency generator and said cable means and said connecting means respectively.

19. The combination according to claim 18, wherein make the combination according to claim 19, comprising an inductive transformer connected to said transformer, said cable means and said connecting means being connected to said inductive transformer. high-frequency generator having an output circuit, said

transformer and said output circuit being tuned in reso-

United States Patent [19]

Roos

4,116,198 [11]

[45]

Sep. 26, 1978

[54]	ELECTRO	- SURGICAL DEVICE	
[75]	Inventor:	Eberhard Roos, Tuttlingen, Fed. Rep. of Germany	
[73]	Assignee:	DELMA, elektro und medizinische Apparatebaugesellschaft m.b.H., Tuttlingen, Fed. Rep. of Germany	
[21]	Appl. No.:	686,600	
[22]	Filed:	May 14, 1976	
[30]	Foreig	n Application Priority Data	
Ma	y 15, 1975 [D	E] Fed. Rep. of Germany 2521719	
[51] [52] ·[58]	U.S. Cl		
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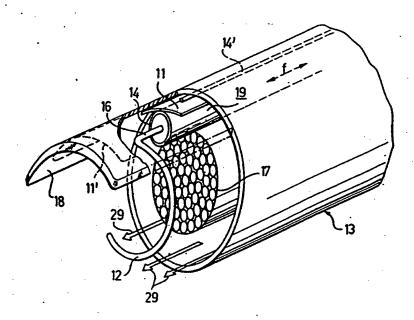
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Primary Examiner-Lee S. Cohen

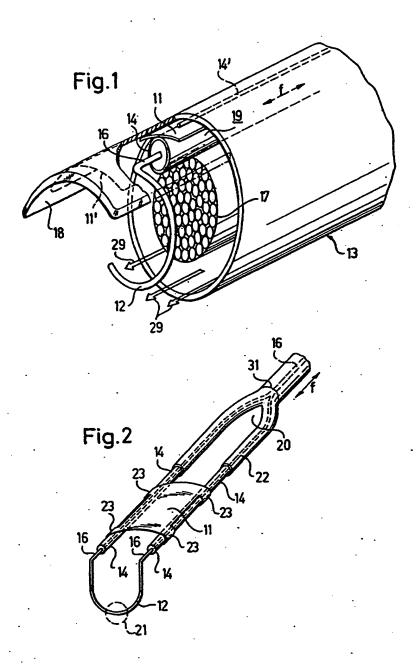
[57] **ABSTRACT**

Electro-surgical device with an insulated cable which can be passed through an endoscope, to which can be connected the pole of a high frequency generator, said pole being insulated from earth potential and on whose end facing the body cavity is provided a small-area treatment electrode projecting from the endoscope, said treatment electrode cooperating with a large-area neutral electrode connected to the other pole of the high frequency generator which is insulated from earth potential in such a way that due to the high current density in the area of the treatment electrode, a generation of heat takes place which is adequate for separating or coagulating tissue, wherein the large-area neutral electrode is arranged in the vicinity of the treatment electrode and is connected with the other pole of the high frequency generator by means of an insulated cable which can also be passed through the endoscope.

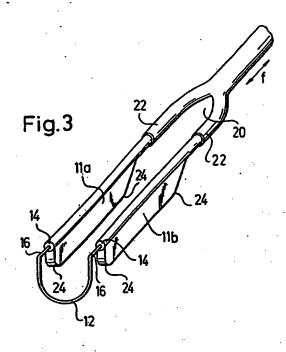
20 Claims, 9 Drawing Figures

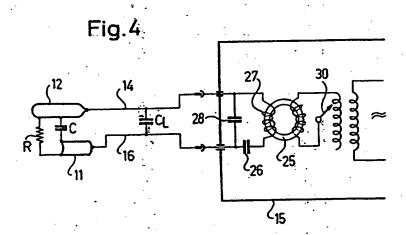


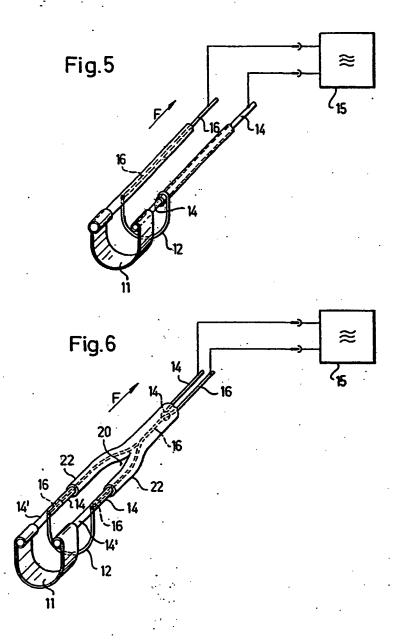




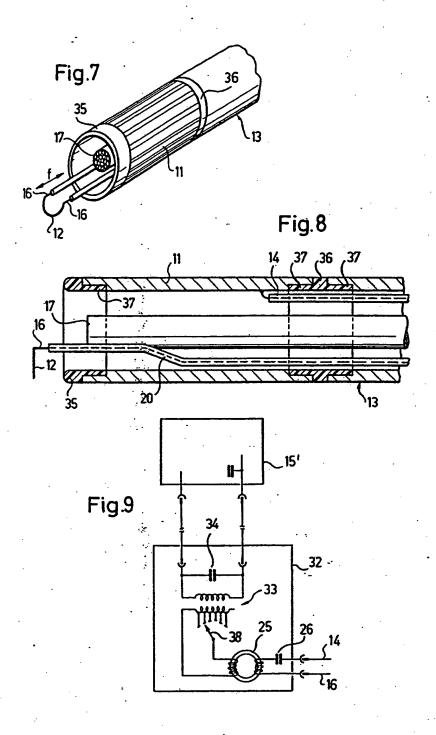








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ELECTRO - SURGICAL DEVICE

BACKGROUND OF THE INVENTION

The invention relates to an electro-surgical device 5 with an insulated cable which can be passed through an endoscope, to which can be connected the pole of a high frequency generator, said pole being insulated from earth potential and on whose end facing the body jecting from the endoscope, said treatment electrode cooperating with a large-area neutral electrode connected to the other pole of the high frequency generator which is insulated from earth potential in such a way that due to the high current density in the area of the 15 treatment electrode, a generation of heat takes place which is adequate for separating or coagulating tissue.

Electro-surgical devices of this type permit electrosurgical operations of the filled bladder (electro-resection, e.g. of bladder tumors and the prostate glands) 20 before where undesired burns to the urethra and the using endoscopes, particularly resectoscopes and cysto-

The high degree of development in the endoscope field has resulted in operations in the bladder and on the prostate glands using these instruments and by means of 25 electro-surgery have become the most commonly used operating procedure.

In known devices of this type, high frequency alternating current is fed via an earthed neutral electrode on the one hand and via a sparking ball or cutting loop well 30 insulated relative to the outer shaft of the endoscope on the other to the operating area for coagulation purposes in the case of hemorrhages. Due to the relatively small area of the cutting loop compared to the area of the neutral electrode applied externally to the patient's 3 body a very high current density occurs in the area of the cutting loop which results in heat generation in the tissue linked with the bursting of the tissue cells through steam generation and consequently a separation of the tissues. For the desired cutting or coagulating effects, the necessary power values of the high frequency current applied vary between 120 and 150 W.

As the leads from the high frequency generator to the cutting electrode have to be passed through the metallic endoscope, the distances between the high frequency- 4 carrying lead and the remaining metal parts of the endoscope insulated therefrom are so small that capacitances of considerable size exist between these metal parts. Thus, to a certain extent, the endoscope forms a capacitor via which part of the applied capacity flows away as 50 leakage current onto the tissue engaging with the metal endoscope shaft. A further, still larger portion of the applied capacity flows from the cutting loop via the washing water directly to the metal parts of the endoscope shaft located in the washing water flow and from 55 there to the engaging tissue. Thus, uncontrollable electrical conditions in the urethral tissue engaging with the endoscope and the unequal distribution of lubricants with insulating properties on the endoscope shaft can cause critical current densities when the leakage current 60 passes to the urethra and this results in burns.

These difficulties would not be eliminated by coating the endoscope shaft with tubes of high-grade insulating material, because the slightest damage to the shaft insulation due to the very high current densities occur dur- 65 ing the passage of the leakage current would, in fact, increase the danger of burning due to the damage. However, if the endoscope shaft insulation remains intact,

the entire leakage current is led off to the points where the operator is in contact with the endoscope leading to burns to the operator's face or to the eye in contact with the metal escutcheons of the transparent optics.

Neutral electrode isolation from earth potential cannot prevent the passage of the leakage currents to the operator. As the neutral electrode acts as an opposite pole to the cutting or coagulation electrode between the patient and the earthed operating table, it is capacitively cavity is provided a small-area treatment electrode pro- 10 connected to earth potential. Therefore, the cutting loop and the leakage current flown therefrom together with its voltage are earthed. Since, in any case, the operator largely carries the earth potential, the passage of the leakage current to the operator cannot be avoided by the measures in question.

BRIEF SUMMARY OF THE INVENTION

The problem of the invention is therefore to provide an electro-surgical device of the type indicated hereinoperator are effectively avoided.

According to the invention, this problem is solved in that the large-area neutral electrode is arranged in the vicinity of the treatment electrode and is connected with the other pole of the high frequency generator by means of an insulated cable which can also be passed through the endoscope. In this way, potential compensation takes place in a spatially very narrowly defined zone. Both the treatment electrode, preferably constructed as a cutting loop and the neutral electrode carry no potential to earth. Leakage current does not flow to the endoscope shaft either from the high frequency lead to the treatment electrode or from the lead to the neutral electrode. Due to the existing capacitance, leakage currents only flow between the leads, but these do not have any external effects.

However, due to the small-area construction of the treatment electrode, a high current density is obtained there, which is adequate for tissue separation or coagulation, whereas the neutral electrode arranged in the immediate vicinity has such a large area that undesired heating is avoided there.

According to a preferred embodiment, the two feed leads comprise a coaxial cable, whose shield forms one conductor and is insulated relative to the endoscope. Thus, the two high frequency leads for the treatment and neutral electrode form a structural unit, which whilst taking up only a small amount of space, can be simply passed through the endoscope together with the optical and washing portions.

In general, the treatment electrode should be in loop form so that the operator's field of vision is uninter-

According to a further embodiment, the centre conductor of the coaxial cable at the front projects above the shield and at this point passes into the treatment electrode. It is thereby particularly advantageous if the shield is constructed as a rigid sleeve and in such a way that the treatment electrode can be moved backwards and forwards relative to the endoscope via the coaxial cable. Thus, in this embodiment, the coaxial cable at the same time forms the support and operating member for the treatment electrode.

The relatively large neutral electrode is advantageously directly fixed to the coaxial cable shield. In this way the neutral electrode can be mounted reliably and immovably in an inexpensive and uncomplicated man-

Advantageously, the neutral electrode is constructed as an elongated metal sheet slightly curved about the endoscope shaft and extending on either side over the coaxial cable.

According to a further advantageous embodiment, 5 the endoscope has a plastic extension extending over a small portion only of its periphery, whereby the treatment electrode can be moved backwards and forwards beneath the said extension. This plastic extension has the advantage that the washing liquid can be satisfacto. 10 the output winding of the transmitter which with the rily guided and tissue which is not to be treated can be kept away from the treatment electrode. According to the invention, this extension can be used so that the large-area neutral electrode is fixed in insulated manner relative to the endoscope on the inside of the extension. 15 The neutral electrode in then preferably connected with the high frequency generator by an insulated cable secured in the endoscope. In this case, only the other

According to a particularly preferred embodiment, the coaxial cable has a bifurcation just before the bodyside end of the endoscope and the two inner conductors eminating from the bifurcation are interconnected by a loop forming the treatment electrode. This construction is particularly stable due to the symmetry conditions resulting from the bifurcation, whereby at the same time the operator still has good visibility through the cutting loop forming the treatment electrode.

If the treatment electrode is used for coagulation 30 purposes, a coagulation sparking ball is fitted to the

treatment electrode.

The coaxial cable is advantageously surrounded by an insulating lead so as to prevent any connection of the 35 endoscope metal with the high frequency voltage. Preferably, the insulating sleeve of the bifurcated coaxial cable is also bifurcated, but it extends only to just in front of the neutral electrode.

In the case of the bifurcated coaxial cable, the neutral 40 electrode is preferably an elongated metal sheet, bent slightly around the endoscope shaft and extending from one branch of the bifurcation to the other. The sheet can have projections at the four corners which are placed around the shields. Depending on the degree of 45 placing around and also clamping, any desired fixing of the neutral electrode to the coaxial cable can be obtained

The current density in the area of the operating zone is advantageously influenced if the neutral electrode 50 terminates at a distance from the end of the shield.

According to a further advantageous embodiment, the neutral electrode comprises two partial electrodes extending in the direction of the loop away from the two arms of the bifurcation. Preferably, the partial elec- 55 trodes do not extend quite as far from the shields as the loop. At the front and rear ends the sheets preferably have rounded portions.

As a result of the slide-like construction, the operator can reliably guide the endoscope by placing the slide- 60 like sheet projections on the tissue to then be removed. As is known, the endoscope is operated in such a way that the cutting loop is moved forwards relative to the endoscope, made live and then slowly retracted, whereby the tissue is removed by the heating on the 65 and 3. cutting loop.

As stated hereinbefore, the treatment electrode and neutral electrode are appropriately so shaped and positioned that the illumination, vision and washing operations are not impaired by the endoscope.

Advantageously, the leads are inductively connected to the high frequency generator, whereby advantageously, a capacitor for filtering out low frequency voltage portions is preserably provided in one lead. This, in advantageous manner avoids faradic effects in the muscular system of the patient.

A capacitor is appropriately connected in parallel to inductor of the latter forms an oscillating circuit which is tuned in such a way that the attenuation in the oscillating circuit formed by the leads, treatment electrode and neutral electrode is minimal.

BRIEF DESCRIPTION OF THE DRAWINGS

Other and further objects of the present invention will be apparent from the following description and conductor with its insulation and treatment electrode is
which, by way of illustration show preferred embodiments of the present invention and the principles thereof and what are now considered to be the best modes contemplated for applying these principles. Other embodiments of the invention embodying the same or equivalent principles may be used and structural changes may be made if desired by those skilled in the art without departing from the invention and the scope of the appended claims.

In the drawings show:

FIG. 1 a schematic, greatly enlarged perspective view of the front end of an endoscope equipped with the electro-surgical device according to the invention.

FIG. 2 a perspective view of a further embodiment of the electro-surgical device according to the invention, without the endoscope surrounding the same.

FIG. 3 a further embodiment of the electro-surgical device according to the invention, once again without a surrounding endoscope.

FIG. 4 a schematic circuit diagram of the electro-surgical device according to the invention with a particularly suitable high frequency generator.

FIGS. 5 and 6 perspective views of two further advantageous embodiments

FIGS. 7 and 8 a perspective view and an axial section of a further advantageous embodiment.

FIG. 9 a schematic circuit diagram of an additional device for the device according to the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

According to FIG. 1, an endoscope 13 is axial traversed in conventional manner by a fibre optical system 17, which is spaced relative to the sides of the endoscope 13, in such a way that washing liquid can pass through there (arrow 29) and there still remains space for the axial insertion of an electro-surgical treatment

According to the invention, this electro-surgical treatment device comprises a coaxial cable 19 with rigid metallic shield 14 and an inner conductor 16 axially inserted together with the fibre optical system 17. Inside the metallic shaft of the endoscope 13, the shield 14 is covered in not shown manner with an insulating sleeve 22, shown in the case of the constructions of FIGS. 2

At the front, inner conductor 16 projects somewhat from the coaxial cable 19 and passes into the treatment electrode 12, which in general comprises a loop ensuring free visibility for the operator via the fibre optical

The opposite electrode for the cutting electrode 12 is formed by a neutral electrode 11 fixed in electrically conductive manner to shield 14 and which is curved 5 somewhat about the endoscope shaft, having a rectangular, elongated form shown in FIG. 1. Inner conductor 16 and shield 14 are connected, as shown in FIG. 4 to the two poles of a high frequency generator 15 which are not at earth potential.

At the front end of the metal shaft of the endoscope 13 is fixed a plastic extension 18, which is rounded and extends in the manner shown in FIG. 1, so as not to impair insertion, for example into the urethra. As the plastic extension 18 is an insulating body, the large-area 15 neutral electrode 11' can also be fitted to the inside. It is then appropriately connected with the associated pole of the high frequency generator via a separate insulated conductor 14' in the endoscope, inside of via the shield

As a result of the construction according to the invention, a high frequency field is only formed between shield 14 and inner conductor 16, as well as between neutral electrode 11 and treatment electrode 12, as is shown schematically in FIG. 4 by capacitors C_L and C. Due to the current conduction through the tissue fluid and tissue itself, a true resistor R is also conceivable parallel to the capacitor between neutral electrode 11 and treatment electrode 12.

The supply to connect neutral electrode 11 and the treatment electrode 12 takes place by the inductive coupling of a high frequency voltage by means of a transformer 25, whose input voltage is regulatble by a put lines 14 and 16 are galvanically isolated from earth potential.

A capacitor 26 connected in lead 16 is used for filtering out the low frequency current and therefore avoids faradic effects in the muscular system of the patient. A 40 capacitor 28 connected in parallel to the output winding 27 of transformer 25 and behind capacitor 26 forms with the output winding an oscillating circuit tuned in such a way that the attenuation in the oscillating circuit lines 14, 16 is minimal.

As a result of the construction according to the invention, the leakage currents only flow between lines 14, 16 and therefore do not reach the metal shaft of endoscope 13. Thus, larger current densities such as are 50 necessary for tissue separation or coagulation only occur outside the endoscope in the operating area.

Therefore, the danger of heating outside the desired area, as well as burns to the operator is reliably avoided.

FIG. 2 shows a particularly advantageous embodi- 55 ment of the electro-surgical device according to the invention in which both the inner conductor 16 and the shield 14 have a bifurcation 20. I, the same way, the insulating sleeve drawn over the shield 14 is bifurcated. The production of such a bifurcation is advantageously 60 obtained by a welded joint at point 31 indicated by a line.

As a result of the bifurcation shown in FIG. 2, a cutting loop 12 can be arranged in the shown manner between the two inner conductors 16 eminating at the 65 end. If the treatment electrode is to be used for coagulation, a coagulation sparking ball 21 can be provided on loop 12.

The construction of FIG. 2 is particularly well suited to the arrangement of a relatively large-area neutral electrode 11 which appropriately extends between the shields 14 of the two branches of the bifurcation 20, being slightly bent about the endoscope shaft. At the end, the neutral electrode 11 has projections 23 which are securely placed around the shields 14 for securing neutral electrodes 11 and for supplying the same with voltage. The metal sheeting forming the neutral elec-10 trode simultaneously constructionally reinforces the bifurcation 20, so that the guidance of the treatment electrode 12 by the operator is aided. As is known, the axial movement of the electro-surgical device in the direction of the double arrow f takes place by operating a pistol-like handle on endoscope 13, not shown in the

A further advantageous embodiment is shown in FIG. 3 where the neutral electrode is broken up into two partial electrodes 11a, 11b, which in the represented manner are soldered or welded to the shields 14 in such a way that the partial electrodes extend in the same direction as cutting loop 12. Rounded portions 24 are provided at both ends. The partial electrodes 11a. 11b applied to the shields 14 in this way thus additionally form slide-like support, by means of which the electro-surgical device can be placed on the tissue to be removed. This not only ensures a reliable guidance of the device but also ensures that the tissue is removed to the predetermined depth. The electrical advantages of limiting current conduction to the operating area are completely maintained.

FIG. 5 shows a further advantageous embodiment, whereby only the front part of the electro-surgical device without the endoscope is shown. In this embodivariable tap 30. Due to the inductive coupling, the out- 35 ment, two insulated cables with inner conductors 14, 16 are passed from high frequency generator 15 through the endoscope. At the front end are successively arranged the cutting loop 12 and the neutral electrode 11 constructed as a steel band. The cutting loop 12 is electrically conductively connected with the inner conductor 16, but at the other end is only fixed to the insulation surrounding the conductor 14. Conversely, the steel band 11, whose shape is similar to the cutting loop 12, is connected in electrically conductive and mechanically formed from C, C and R as well as the inductors of 45 secure manner with the inner conductor 14, whilst the opposite end is mechanically secured to the insulation of the inner conductor 16. Since, according to the invention, the steel band 11 has the same radius as the wire loop, on retracting the loop 12 in the direction of arrow F, the band does not form an obstacle to the tissue portions removed by the loop. The neutral electrode 11 in the form of the steel band rests on the tissue in large-

area form, so that good electrical contact is ensured. FIG. 6 shows an embodiment which is substantially the same as FIG. 5, whereby however, a bifurcated coaxial cable, similar to FIGS. 2 and 3 is used. The wire loop 12 is once again fixed to the inner conductors 16, whilst the neutral conductor 11 in band form is mechanically secured to extensions 14' electrically connected with the shield 14.

In the embodiment according to FIGS. 7 and 8, the front portion of endoscope 13 itself or a coaxial connection attached thereto at the front is constructed as the neutral electrode 11. To this end, the front portion is electrically insulated relative to the rear portion or the front-fitted connection from endoscope 13 by an intermediately inserted insulating ring 36. The cutting loop 12 can at the front be passed out of the neutral electrode 11 in one of the above-described manners. In the present embodiment, two leads 16 pass outwards from the cylindrical neutral electrode 11, which at 20 are combined to form a single cable, leading to the rear end of endoscope 13. The neutral electrode 11 is connected via a 5 further insulated cable 14 to the high frequency generator 15 not shown in FIGS. 7 and 8.

It is also important in the case of the embodiments of FIGS. 7 and 8 that the cutting loop extends radially up to an insulating ring 35 mounted at the front on the 10 neutral electrode 11 and can be retracted up to this. In this way, the front edge of the endoscope shaft, namely the front edge of the insulating ring 35 serves as a support for the cutting loop 12, so that the material is reliably removed therefrom. Therefore, as shown the insu- 15 lating ring 35 must be rounded at the front.

Preferably, the insulating rings 35, 36 have axial attachments 37 with a reduced external diameter, by means of which a machanically secure fixing to the

metal tubes is ensured.

FIG. 9 shows an additional device 32, by means of which a conventional high frequency surgical apparatus 15' with an earthed output terminal can be made usable for the purposes of the invention. The additional device 32 connected to the high frequency apparatus 15' has at 25 the inlet a transformer 33 with parallel-connected capacitor 34 for tuning to the resonant frequency of the output circuit of the high frequency apparatus 15'. The output winding of transformer 33 is preferably regulatable by means of a loop arm 38 in such a way that the 30 inductive output transformer 25 can receive voltages of varving sizes.

Via a capacitor 26, the output winding of transformer 25 is applied to the two output terminals of the additional device 32, where the leads 14, 16 can be applied. 35

In this way the high frequency apparatus 15' acquires an output with fluctuating potential, as is necessary for the connection of the electro-surgical device according to the invention.

The invention is not limited to the embodiments de- 40 scribed and represented hereinbefore and various modifications can be made thereto without passing beyond the scope of the invention.

What is claimed is:

1. In combination: an endoscope having an endoscope 45 body of substantially tubular shape, and an electro-surgical device comprising a treatment electrode projecting at one end from said endoscope body and a neutral electrode arranged adjacent said treatment electrode, insulated cable means for connecting said treatment 50 electrode to one pole of a high-frequency generator, and means for connecting said neutral electrode to the other pole of a high-frequency generator, said endoscope body having an-insulating projection extending over a portion of the periphery of said endoscope body 55 said connecting means for filtering out low-frequency at said one end and having a front edge, said neutral electrode being located within said endoscope body and spaced a distinct distance inwardly from said front edge, a space being formed between said treatment electrode and said neutral electrode which is adapted to 60 be filled with liquid to provide electrical conductance between said electrodes

2. The combination of claim 1, wherein said insulated cable means and said means for connecting said neutral electrode to said other pole comprise coaxial cable 65 means with shielding means forming one of said connecting means and being insulated relative to said endoscope body.

3. The combination according to claim 2, wherein said shielding means is constructed as a rigid sleeve in which said treatment electrode is adapted to be moved back and forth relative to said endoscope body through said coaxial cable means.

4. The combination according to claim 2, wherein said neutral electrode is fixed directly to said shielding

means of said coaxial cable means.

5. The combination according to claim 4, wherein the neutral electrode is constructed as an elongated metal sheet slightly bent within said endoscope body and extending over said coaxial cable means.

6. The combination according to claim 2, comprising an insulating sleeve surrounding said coaxial cable

means.

7. The combination according to claim 6, wherein said insulating sleeve is bifurcated and extends approximately to said neutral electrode.

8. The combination according to claim 7, wherein said neutral electrode is an elongated metal sheet slightly bent within said endoscope body and extending from one branch of said bifurcated insulating sleeve to the other.

9. The combination according to claim 8, wherein said sheet has projections at its four corners, two each of which are placed around the respective branches of said bifurcated sleeve.

10. The combination according to claim 2, wherein said neutral electrode terminates at a distance from said

shielding means.

11. The combination according to claim 1, wherein said neutral electrode is secured to and insulated from said endoscope body on the inside of said insulating projection.

12. The combination according to claim 1, wherein said means for connecting said neutral electrode to said high-frequency generator is an insulated conductor

secured in said endoscope body.

13. The combination according to claim 2, wherein said coaxial cable means has a bifurcation at that end of the endoscope body adjacent said projection, two inner conductors eminating from said bifurcation, and a loop interconnecting said two inner conductors and forming said treatment electrode.

14. The combination according to claim 1, wherein a coagulation sparking ball is fitted to said treatment elec-

trode.

15. The combination according to claim 1, comprising a high-frequency generator, and wherein said cable means and said connecting means are inductively coupled to said high-frequency generator.

16. The combination according to claim 15, wherein a capacitor is connected in one of said cable means and

17. The combination according to claim 15, wherein said generator comprises a transformer with an output winding having an inductor, a capacitor being connected parallel to said output winding and forming an oscillating circuit with said inductor, said circuit being tuned such that the attenuation in said circuit formed by said cable means, said connecting means, treatment electrode and neutral electrode is minimal.

18. The combination according to claim 15, comprising means for potential isolation connected between said high-frequency generator and said cable means and

said connecting means respectively.

19. The combination according to claim 18, wherein said potential isolation means comprises a transformer, a capacitor connected parallel to said transformer, said 5 high-frequency generator having an output circuit, said

transformer and said output circuit being tuned in resonance.

20. The combination according to claim 19, comprising an inductive transformer connected to said transformer, said cable means and said connecting means being connected to said inductive transformer.

Über ein Instrument zur leckstromfreien transurethralen Resektion -

Von E. ELSASSER und E. ROOS

Krankenheus der Bernherzigen Brüder, Urologische Abteilung, München, Chefärzte, Priv. Dez. E. Eleite

transurethrales alektrochlostylschan Operationen - melst Resektionen an Prostata oder Hambiase -- tretan in nicht zu unterschätzender Häufigkeit Hamrohrenstnikhiren auf, die mit größtor Wahrschemitchkeit als die Folge von Stromvedetzungen der Harniöhre angeworden müssen (ELSASSER, ROOS, SCHWIEDT).

Bel allen chlaurglachen Eingritten selt hochfrequentem Wechselstrom wird der Organismus des Kranken Tell eines Stromkreisen: Der vom Generator gelleforte Hochirequenzatrom tritt am der punktionugen Schneideelektrode In don Organismus ele und fließt auf Im einzelnen unbekannten Wegen 23 der prostischigen, insktiven, innerhalb des HT-Generators geerdeten Neutral trode and damit zum Erdpotentiel (BBd 1).

Unmittelber unter der punktionnigen Aktivelektrode trifft der mit hoher Dichte eintretende Strom auf den hohen elektrischen Widerstand des Gewebes. Nach dem JOULEschen Gesetz Wilrene -

Stiomstärke² × Widerstand × Zalt e wickeln sich im Gewebe unter der Aktivelektrode so hohe Ten es durch Verdamptong von solgkeit zur Sprengung der G treider und dereit zur bes aich der Strom in der Regel solort in be apphreliet, pirmet er sehr react an Dichte ab und wird daher auf sei nem welteren Weg durch den Organis mus zur Neutraleisktrode erscheim frei vertragen.

CARDIOL eta-system



jetzt noch attraktiver für Sie REME



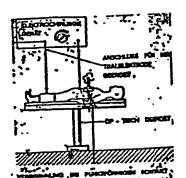










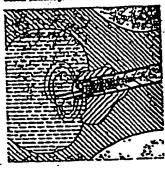


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Entsprechend den elektrophysitzlischen Gesetzen schligt der Strom siets den Weg des geringsten Widerstandet zim Potentialzusgleich est. in der Regel wird Rim dieser Weg in Form der Houtralelektrode angeboten (Bdd 1).

Homent der Patient aber seit anderen geerdeten Metaliteten — etwa des Operationstischen — in Berühung, ab izen der Strom seich dort zur Erde abtließen, and dies um ao sher, wenn denrüge Berührungspunkte dem Operationage-biet acht sein gelegen sind oder wenn die Neutraleisktrode durch unsechgematië Ficherung dem Strombbegung aben höheren Vriderstand entgeperatzt. Sind derartige Kontakintälen mit geerdaten Leham zur jelentächig, so wird hier die Strombiete ennet sehr hoch und es hann zu Verbrenzungen hommen (Bild I).

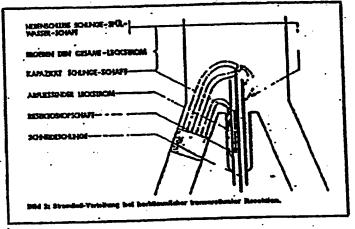
Stal Is Street-in-inchang der Hauselber bei ber hillmaticher Till durch Lader-Steet Anfeit der hapenfelsen Leinkeinen Stott der Breun dirch von der Rechnelsseddings und die in den hiel manner hindersenschapen Tille den Reselbstehape



Diese prinzipielle Gelahr von unbelabalchtigten Stromverletzungen des Gewebes abselts vom Operationsgebiet int apsziell bei urologischen Eingriffen aus dreieriet Gründen besonders hocht

- 1. For die Schnitz und Koagutztionen unter Wasser werden besonders bohe Stromapphilationen benotigi
- 2. Die ublichen Resektiskope, die 818 atromkihrenden (Schneideschinge) und nichtstromivitrenden Metaliteillen Busammeagesetzt sind, etsten Kondunstoren der, die einen kapazitiven Unserging des Hochtrequenzistromes auch auf die von den stromführenden Elementen leotiertan Metaliteile zutassen.

ELSXSSER, ROOS and SCHMEDT vieses 1974 dersal hir, daß etwa 20% der auf die Schneidschinge applichten Hordrequemicishing kapazinv ein 80gunannter "Lackstrom" an den Reselvlookopschaft verforengeben. Oberfische eine Inaldive Elektrode desstellt, Wenn sich der Stromübertritt jedoch aus argendereichen Gründen (vorbeviehende Harmschrenstrikter, Läcke im lealerenders Gieltmittelfilm) bevorzugt -- eder ger ausschileßich -emer kleinen, circumskinplan Schaltsielle ereignet, wird die an dieser Stalle zu hohe Stromdichte zu elektrotherseschor Schädigung des Gewebes führen Aufgrund der besonderen anatomiechen Gagabanhadan berm Mann - die merstern prologischen Patienten and ja Mérmer - muß außerdem die Sm aller an die Hernrohre abgegebesen Lackstrome, bevor sie sich im kleinen Becken ausbreiten Manen, die Penswurzel passieren, so daß die Harneth im Bereich dieses Engpasses zwangs litting einer beconders hohen Strombelantung ausgewetzt sein mill. die unter Umetänden individuell nicht mehr below trahelor



Neuere und weltergebande Universuchungen am Pierten (Roos) haben ergeben, das zusätzlich — durch Nebenschlaß über des Späirezser — Strom von der Schreidschänge auf die von Späirezser umfluteten Resektoskopinäte (Schalt und Optid) übergeben kurn. Der Piesektoskopinäte und des des auwohl kunzutte wie über des Späirezser artestich aufgelnden (Bilder Z, 3 und 4).

3. Die Summe der Leckströme Melli über des dem Schaft antilegende Hessröhrungewebe zur Neutraleitektrode, weiin der Regel unbemerkt und obne neutteilige Folgen geschieht, well der Reseldostupschieft unt seiner großes Um die Harnrühre vor dieser hohen Strombelestung mit möglicher elektrethermischer Schädigung zu schätzen, wurden in letzter Zeit Reselutoshope gebeurt, deren Schaft ertweder panz aus nichtleitendem Maturial (Teffort[®]) betieltt oder durch elden Überzug mit einem Teitonschinuch inollert wird.

Aber auch solche Resektoskope eind in ihrer Anwendung nicht rielkolost Der richtlistende Schaft verhindert zwir den Dbertritt der Leckstrome vom Resektoskopschaft uuf die Harmohre, richt aber die kapazitiva Aulkalang der in Inneren den Schaftes gelegenen Metallielle, De der Petentialsungtenh über

Medizinal-Marki / Acta Medicotechnica • 24 Jehrpang, Nr. 4/1976

Harnröhre und Neutraleicktrode durch die Isobening verhindert wird, aucht alch der Leckstrom einen anderen Weg zur Erde. Dieser Weg führt zwangelaung über den Operateur, der durch seine nicht vermoldbare erhebbche Körperkapszdat gagenüber dem Massepok ted als Ober einen sicht sehr hohen Widerstand geerdet angesahen werden muß. Unangenehme und zum Tell nicht ungefahrliche Entischingserscheinungen Im Geaicht des Operateurs sind des Folge (BBd 8) Auch an anderen Stellon, z.B. bol Berühnung der Arme des Operateurs and des geordeten Armstitzon des Operationstisches, sind punktformige Entladungen hikifig.

Aber auch der Kranku kann Stromverletzungen erteiden: Wenn bei Falköv langern Penla das instrement bei eingehüht werden mid, kann se -- wie in einem eigenen Fall -- durch Kontakt der Glans mid des Mejalkoten am Ende des Tellooschattes zur zirkulären Verbrennung um den Mestus extamus herum kommen, Besonders gefährlich

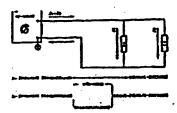


Bild & BrooksakaMbild an den Bildom 2 und

lid die Verwindung von Instrumenten mit inflenbeschichtetern. Metaltschaft: Robiste Delekte in der Teilenbeschichtung werden seiert zum Ort Intensiven Stromfühertrites und Thermoelektrischer Schädigung der Harmötire.

Hachdem es offensichtlich pilcht gefingt, Lackströme durch inollerung enzudistmen, acheint es nahellegand, den umgetahrten Weg zu beschraften: nilmlich dem Hochfrequenzstrom einem eo kurzen und viderstandsamen Weg zum Potendistspielch anzubisten, daß aberrierende Ströme oder Lackströme gar nicht auftrette.

Dies geschieht

f. durch extreme raumhche Annkherung der inektiven, großtlächigen Heubraisitztrode an die aktive Schneidelektrode, die einen Potentialkungsleich twischen beiden Elektroden auf engatem Faum, d. h. innerhalb des Operahonzpobietes, also der Hambisse, ermöglicht, ohne daß endere Dewebebezirke in die Strömbehn einbezogen werden. Der Strom fiedt von der Schneideschlinge derch das anliegende, zu schaeldende Gewebe und das Spititrode,

 durch den Auschtuß beider Elektroden an einen Hochtrequenzgenerater mit erdschlußtreiem, schwebendem Ausgangskreis, sog. "floating output".

Da in diesem erdschistlireien Ausgengskreis keine der Elektroderzusiestungen Erdpotentiel Wist, besteht auch teilne Spannung gegen des Erdpotentiel. Es kann alch somit lein Stromfluß vom Operationsfeld zur Erde ausbilden,



Dieses Prinzip der Verwendung von blpolar susgebilderen Elektroden in Verbindung mit einem entschätsfreien,
schwebenden Hochfrequenzstromkreis
haben im Bareich der Gynäkologie
HIRSCH und ROOS zur laparoekopischen Tubenzhriffsstion und MELCHOR
für die Blutztinung durch bipolare
Mikrokoeguiston beschrieben

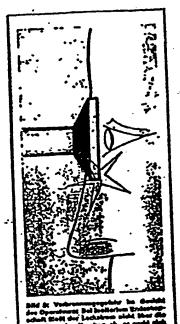
Am urologischen Resektoskop können Neutraleiskirode und Aldresiskirode konstruktiv zu einer bipolaran Elektrode vereinigt werden, indem die Neutralelskirode — wie die Bilder 6 und 7 zeipen — als Metaliplatie der Schinekteschlinge aufgesetzt wird.

Diase Konstruktion als bipolare Enstrude bretet operationstachritisch jedoch einige Bichwiengkeitent Durch die Anordnung des profiliächigen Metalpitällichen oberhalb der Schneidsschlunge werden ottensichtlich die Stromungsverhältnisse gestört, so daß durch Blasenbildungen im Spülwasser die Sicht auf das Operationsleid stark beeinträchtigt wird. Dresse Problem let jedoch mögscherweise von einem erfahrenen Resektoskophersbiller zu 10een.

Eine zweite Möglichkeit, die Neutraleiektrude als Netaltring in das blassenahe Ende des Resektoskopechaltes einzubesen (Bilder 8 und 1), hat elch dagegen operationetechnisch eis prebiemios erwiesen und gut beseitzt.

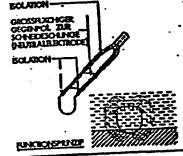
Schon Messungen am Phantom habert pezalgt, daß sowohl bei Yennendeng der bipoleren wie der fringelektrode durch die neuerige Stromithrung sehr secherte werden. Der Resektneisen perchaffen werden. Der Resektneisen schefft und das ihm sallegende Gewebe untertiegen isber Belantung durch Lackströme, der Organismus ist — mit Auenahme des kielnen Bezittes zwischen den beiden Elektroden — nicht in den Stromituse eingescheitet, abserterende Ströme hönnen nur in minimaker Stärte abgeleitet bzw. gemessen werden.

Wir haben ein berkömmliches Resekteskop mit einem derartigen, die Neutrelelektrode tragenden Resektoekopschelk, wie ihn die Bilder 8 und 8 zeigen, versehen und die normale Schnelde-



schinge dieses Resolduskopes was such die Neutraleistrade an sin von der Firms Marike'j zur Verbigung gestelles, an die besonderen elektrischen Verhält-

2Md in Bholoro Bickiroden-Anarchiung meth Schmolden bel trainerstreiter Beackloot Der Street Stadi van der Schmoldenchlope chroli Der der nahm beliebenigen Hentspielekonde.

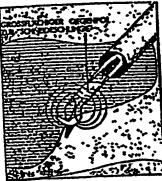


nisse angepatites HF-Chirurglegerit mit "Hosting output" angeschlossen.

Mit diesem, von une selbet derart modnizierten instrument (Bader 8 und 9) haben wir bis jetzt insgesamt 27 Elektroresektionen der Proetzta und find der Harnhisse komphikationelos sungeführt. Die Schneidefahsgiseit der Schleige war durch die neue Stromfuhrung in keiner Weise besintrachtsgit Es isseen sech windestene obesen gut wie mit den inframmischen instrumerten mitheles glatta, schorifrele Schnitte ausführen

Dasselbe gilt kir die Bhristiftung, die mit der Kosquistionselektrode ausgezeichnet gehegt.

Zur Prutung der neuen elektrochen Verhältnisse haben wir hei fürst der insgesamt 32 Operierten etstärische Messengen durchgetährt. Die Anordnung der Hobszeinzmente und die Meß-Streckum alnd in Bild 10 wiedergegeben



234 7: Auf engen Ramn elegentelbiles elebbiedes Spannungsfeld bei Veterversendadi.

- In Ableriatron vom Resektoskop 28 einer am Oberschenkal ficierten Neutraleisktrode (hal archimo-Bertsen Schaft Medit deser Ableboder Leckstrom über die Hamphire zur Heutraleisktrode 20-nleich.
- U) = Elektrische Spannung zwischen Persektoskop und der Neutrefelektrode.
- 7 Frent Gebridder MAPIEM, D-7200 Tellinge

Asepsis im OP

Lautenschläger

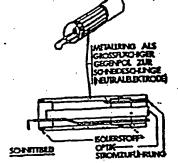
STERILIBIERAPPARATE UNYERS, ANGEBOT DURCH LAUTENSCHLIGER 3222 GENETSRIED S. MONCHEN

Medizinel-Markt / Acta Medicolechnica 24, Jahrgang, Nr. 4/1976

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12 — Ableitstrom vom Resektoskop zur Erde f\(\text{Utsache b\(\text{sidiger}\) Verbrennungen \(\text{kn}\) Gesicht des Opersteurs\(\text{k}\).

U₂ - Elektrische Spennung Zwischen Resektoekop und Erde.



BM & Stockers Elektrodersandrung zur transpropuntien Besentiern Die Heutrablicktode ist zie Meisilchig zur Ende des Beseitsebepochelter meistende. is — Ableitstrom vom Pationise zur Erda fürzache von Verbrankungen des Patienins ber kleinflächsgen Koniektes mit erdpotentishitrenden, intenden Op-Tieth-Tellen).

U₃ = Elektrische Spannung zwischen Patient und Erde

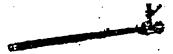
Ala Medinstrumente wurden verwendet:
Strom- Neuberger-Milliamperemeter and Thempokressz.

meter mit The moluteux, Natherelde 0—150 mA ta. 0—600 mA

Spannenge- Kalhodeestrahl-Ostifiomesser graph von Advance Electronica, Type OS 2000

Bel Jedem zu Operiorenden wurden die ersten Schnitte int einem herführenhehen Reseltloniop mit Tellonisollerung zusgeführt und dabei die während des Schneidevorgenges auftretenden Ledeströme und Spannungen gemessen. Abgeleitet wurde von den operateurnehen Metallissien des Instituteries.

Hach Edassung der Maßdaten wurde das Instrument gewechselt und die



Shi in Photographia des instrumentes aus Abbildang in Die Neutraleiskrede sitzi pie Metalldan am Ende den Resettentreschaften.

Operation mit dem neues, von une modifficient. Resektoskop mit bipolaret Stromeppiskation 'und erdschaftmines Hit-Generator mit "Souting output" durchgeführt.

Am gloichen Patienten wurden nummehr unter den gloichen Bedingungen, bei imverknderter Lagerung die gloichen Hessungen während des Schneiderorganges vorgenommen.

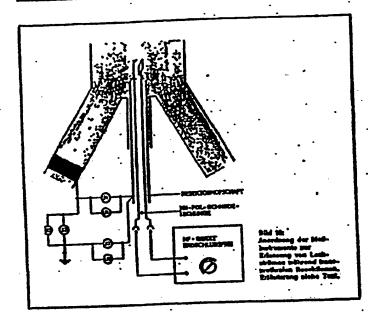
Die Tebelle zeigt des Mittel ein den gewonneren Meßdelen, in der oberen Zelle bei hertifmmilicher Technik, in der unteren Zolle mit dem neuen instrutions.

Der bei konventioneller Technik gemessene Leckstrom ist mit 150 mA so groß,



Tabellet Meddaten, Schaltung siehe Bild 10

Operationatechnik	4	Ui .	b	Uz	6	U ₃
torrentoned, init peerdater New- tratelatorede	i i	kurzgeschioseen beide geerdet 150 mA 300 V			entfällt, direkt korzgeschlossen	
noue bi-polare Technik	15 mA	20 Y	15 mA	20 V	.<2 mA	<10 v



daß an kielntlächigen Kontaktrietien mit geerdeten Laitern uuf jeden Pall mit Varbrennungen gerechset werden mitk, gleichgütig wo desee Kontakt entsteht: Im Beraich der Hamrühre eder der Heist des Krenken oder der Heut des Operateurs.

Die Mobwerte, bei Anwendung der neuen blockeren Technik Hegen unterhalb des kraischen Bersiches, und eie lasses sich mit großer Wahrscheinlichkeit durch konstruktive Verbesserungen me Resektoskop und am Zuleikungekabel noch welter reduzieren.

Zusemmentessung

Es wird über ein Resektoskop mit neuartiger Anerdnung der Elektroden berichtet, des mit einem teckstrondresen Hockfrequenzstronkreis arbeitet. Bieber wurden demit 82 komplikationeloee Reentsionen ausgefährt.

Der Hochfrequenzstrom, der von einem erdschlußirelen Hochtrequenzgenerator mit admebanders Ausgangskreis gellefort wird, filest von der aktiven Schneldeelektrode durch des zu echneldende Gawebe und des Spilwesser dirett zu der ringförmigen, am proxime-ten Ende des Resektoskopechanes ampebrachten Heutralelektrode, Der Stro Stuß im Organismus bleibt auf das kielse Operationsgebiet Innerhalb der Blave schränkt. De die Zufaltungen 29 betden Elektroden keine Spannung geg that des Massapotential (Erdpot aufweisen, kann sich auch kein Str BuS yors Operationsleid bur Erde at bilden. Enterprecised tiberen bei der en Mothodo -- m Gogonsatz zu den herkömmischen -- keine nennens

Ladistrome gemessen werden, die ets Ursache von Stromverletzungen en Harnzohre eder Haut des Kranien in Frage kommen.

Literaturi

- [1] PLREER, E., ROCE, E., u. SCHREET, E.
 Ladistrom miologi impositivos Stratibespanges als Unacche von Haraffernstalllares soch TLIE Yerk Ser Devender Sen-Urel 31 Tg. 1074 Munches, Spranger Verlag Bartes — Hendelberg 1876, p. 46—8
- pp HORSCH, MA, and ROOK, E. Laparethepsche Tuberstenkreiten mit ener seues Bibosyclatensiangs Coburts to Freeseheilt 34, 34—34 (1974)
- PJ MELCHON, N. Buyolate Midrotsopulates. Verb. Bor, Doutsch, Ges, Urel 28 Tg. 1872 Accion. Springer Verlag Burks. — Healthbory 1974, p. 146—148

Keywordst

Lectustromirale transvestirale Assaltion — neves instrument

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Resocción transureiral em luga de corsiente — un nuevo instrumente

Anachritt der Verfasser: Prer-Döz. Dr.E. Ehllisser, Krachschaus der Bermberngen Brüder, Urologische Abtellung, Remenstraße 83, D-8000 München 18.

E. Acce, Ing. VDL, Fa. Gobt. Martin, D-7200 Tuttingen.

Medizinal-Markt/ Acta Medicotechnica

Useare nächste Ausgabe hat "Technische kittel in der Krantenpliege" zum Fachtbenn.
Außerdem berichtet Prof. Dr. Mest
Anhiber, institut für Biomedizielsche Technik der Universität Zilrich und der ETHZ, über neue
diegnostische Verfahren weufe
liber Gerate, die zu seinem institut entwickelt werden.

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Medizinal-Marki / Acta Medicolectroca • 24 Jehrgang, Nr. 4/1976

Über ein Instrument zur leckstromfreien transurethralen Resektion

Von E. ELSASSER und E. ROOS

Krankenhaus der Barmherzigen Brüder, Urologische Abteilung, München, Chefärzte: Priv.-Doz. E. Elsässer / Dr. W. Schneider

Nach transurethralen elektrochirurgischen Operationen — meist Resektionen an Prostata oder Hamblase — treten in nicht zu unterschätzender Häufigkeit Hamröhrenstrikturen auf, die mit größter Wahrscheinlichkeit als die Folge von Stromverletzungen der Hamröhre angesehen werden müssen (ELSÄSSER, ROOS, SCHMIEDT).

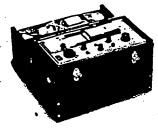
Bei allen chirurgischen Eingriffen mit hochfrequentem Wechselstrom wird der Organismus des Kranken Teil eines Stromkreises: Der vom Generator gelieferte Hochfrequenzstrom tritt an der punktförmigen Schneideelektrode in den Organismus ein und fließt auf im einzelnen unbekannten Wegen zu der großflächigen, inaktiven, innerhalb des HF-Generators geerdeten Neutralelektrode und damit zum Erdpotential (Bild 1).

Unmittelbar unter der punktförmigen Aktivelektrode trifft der mit hoher Dichte eintretende Strom auf den hohen elektrischen Widerstand des Gewebes. Nach dem JOULE'schen Gesetz: Wärme =

Stromstärke² × Widerstand × Zeit entwickeln sich im Gewebe unter der Aktivelektrode so hohe Temperaturen, daß es durch Verdampfung von Gewebsflüssigkeit zur Sprengung der Gewebestruktur und damit zur beabsichtigten Gewebsdurchtrennung kommt. Da sich der Strom in der Regel sofort im Gewebe ausbreitet, nimmt er sehr rasch an Dichte ab und wird daher auf seinem weiteren Weg durch den Organismus zur Neutralelektrode erscheinungsfrei vertragen.

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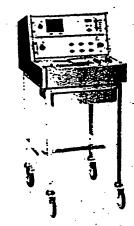


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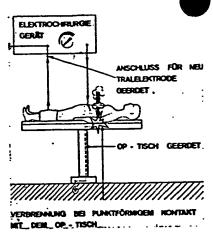
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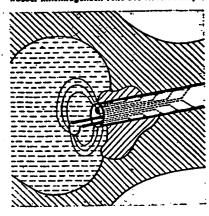


Blid 1: Stromkreis bei Elektrochirurgie mit herkömmlicher geerdeter Neutralelektrode. Der Hochfrequenzstrom fileßt dabei immer von der Aktivelektrode auf dem Weg des geringsten Widerstandes zur Erde.

Entsprechend den elektrophysikalischen Gesetzen schlägt der Strom stets den Weg des geringsten Widerstandes zum Potentialausgleich ein. In der Regel wird ihm dieser Weg in Form der Neutralelektrode angeboten (Bild 1).

Kommt der Patient aber mit anderen geerdeten Metallteilen — etwa des Operationstisches — in Berührung, so kann der Strom auch dort zur Erde abfließen, und dies um so eher, wenn derartige Berührungspunkte dem Operationsgebiet sehr nahe gelegen sind oder wenn die Neutralelektrode durch unsachgemäße Fixierung dem Stromübergang einen höheren Widerstand entgegensetzt. Sind derartige Kontaktstellen mit geerdeten Leitern nur kleinflächig, so wird hier die Stromdichte erneut sehr hoch und es kann zu Verbrennungen kommen (Bild 1).

Bild 3: Strombelastung der Harnröhre bei herkömmlicher TUR durch Leckströme: Außer den kapazitiven Leckstrom fließt der Strom direkt von der Schneldeschlinge auf die in das Spölwasser hinelungenden Telle des Resektoskops

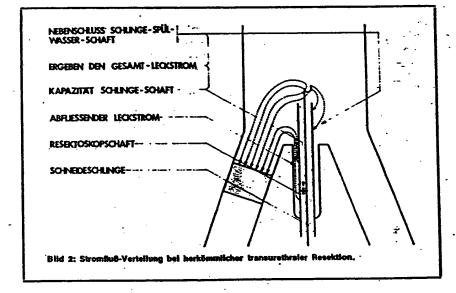


Diese prinzipielle Gefahr von unbeabsichtigten Stromverletzungen des Gewebes abseits vom Operationsgebiet ist speziell bei urologischen Eingriffen aus dreierlei Gründen besonders hoch:

- Für die Schnitte und Koagulationen unter Wasser werden besonders hohe Stromapplikationen benötigt.
- 2. Die üblichen Resektoskope, die aus stromführenden (Schneideschlinge) und nichtstromführenden Metaliteilen zusammengesetzt sind, stellen Kondensatoren dar, die einen kapazitiven Übergang des Hochfrequenzstromes auch auf die von den stromführenden Elementen isolierten Metallteile zulassen.

ELSÄSSER, ROOS und SCHMIEDT wiesen 1974 darauf hin, daß etwa 20% der auf die Schneidschlinge applizierten Hochfrequenzieistung kapazitiv als sogenannter "Leckstrom" an den Resektoskopschaft verlorengehen.

Oberfläche eine inaktive Elektrode darstellt. Wenn sich der Stromübertritt jedoch aus irgendwelchen Gründen (vorbestehende Harnröhrenstriktur, Lücke im isolierenden Gleitmittelfilm) bevorzugt - oder gar ausschließlich - an einer kleinen, circumskripten Schaftstelle ereignet, wird die an dieser Stelle zu hohe Stromdichte zu elektrothermischer Schädigung des Gewebes führen. Aufgrund der besonderen anatomischen Gegebenheiten beim Mann - die meisten urologischen Patienten sind ja Männer - muß außerdem die Summe aller an die Harnröhre abgegebenen Leckströme, bevor sie sich im kleinen Becken ausbreiten können, die Peniswurzel passieren, so daß die Harnröhre im Bereich dieses Engpasses zwangsläufig einer besonders hohen Strombelastung ausgesetzt sein muß, die unter Umständen individuell nicht mehr toleriert wird.



Neuere und weitergehende Untersuchungen am Phantom (Roos) haben ergeben, daß zusätzlich — durch Nebenschluß über das Spülwasser — Strom von der Schneidschlinge auf die von Spülwasser umfluteten Resektoskopteile (Schaft und Optik) übergehen kann. Der Resektoskopschaft wird also sowohl kapazitiv wie über das Spülwasser erheblich aufgeladen (Bilder 2, 3 und 4).

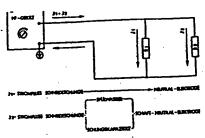
3. Die Summe der Leckströme fließt über das dem Schaft anliegende Harnröhrengewebe zur Neutralelektrode, was in der Regel unbemerkt und ohne nachteilige Folgen geschieht, weil der Resektoskopschaft mit seiner großen Um die Harnröhre vor dieser hohen Strombelastung mit möglicher elektrothermischer Schädigung zu schützen, wurden in letzter Zeit Resektoskope_gebaut, deren Schaft entweder ganz aus nichtleitendem Material (Teflon®) besteht oder durch einen Überzug mit einem Teflonschlauch isoliert wird.

Aber auch solche Resektoskope sind in ihrer Anwendung nicht risikolos: Der nichtleitende Schaft verhindert zwar den Obertritt der Leckströme vom Resektoskopschaft auf die Harnröhre, nicht aber die kapazitive Aufladung der im Inneren des Schaftes gelegenen Metallteile. Da der Potentialausgleich über

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Harnröhre und Neutralelektrode durch die Isolierung verhindert wird. sucht sich der Leckstrom einen anderen Weg zur Erde. Dieser Weg führt zwangsläufig über den Operateur, der durch seine nicht vermeidbare erhebliche Körperkapazität gegenüber dem Massepotential als über einen nicht sehr hohen Widerstand geerdet angesehen werden muß. Unangenehme und zum Teil nicht ungefährliche Entladungserscheinungen im Gesicht des Operateurs sind die Folge (Bild 5). Auch an anderen Stellen, z.B. bei Berührung der Arme des Operateurs mit den geerdeten Armstützen des Operationstisches, sind punktförmige Entladungen häufig.

Aber auch der Kranke kann Stromverletzungen erleiden: Wenn bei relativ langem Penis das Instrument tief eingeführt werden muß, kann es — wie in einem eigenen Fall — durch Kontakt der Glans mit den Metallteilen am Ende des Teflonschaftes zur zirkulären Verbrennung um den Meatus externus herum kommen. Besonders gefährlich



Blid 4; Ersatzschaltbild zu den Bildern 2 und 3.

ist die Verwendung von Instrumenten mit teflonbeschichtetem Metallschaft: Kleinste Defekte in der Teflonbeschichtung werden sofort zum Ort intensiven Stromübertrittes und thermoelektrischer Schädigung der Harnröhre.

Nachdem es offensichtlich nicht gelingt, Leckströme durch Isolierung einzudämmen, scheint es naheliegend, den umgekehrten Weg zu beschreiten: nämlich dem Hochfrequenzstrom einen so kurzen und widerstandsarmen Weg zum Potentialausgleich anzubieten, daß aberrierende Ströme oder Leckströme gar nicht auftreten.

Dies geschieht

1. durch extreme räumliche Annäherung der inaktiven, großlächigen Neutralelektrode an die aktive Schneidelektrode, die einen Potentialausgleich zwischen beiden Elektroden auf engstem Raum, d. h. innerhalb des Operationsgebietes, also der Hamblase, ermöglicht, ohne daß andere Gewebsbezirke in die Strombahn einbezogen werden. Der Strom fließt von der Schneideschlinge durch das anliegende, zu schneidende Gewebe und das Spülwasser unmittelbar zur Neutralelektrode.

 durch den Anschluß beider Elektroden an einen Hochfrequenzgenerator mit erdschlußfreiem, schwebendem Ausgangskreis, sog. "floating output".

Da in diesem erdschlußfreien Ausgangskreis keine der Elektrodenzuleitungen Erdpotential führt, besteht auch keine Spannung gegen das Erdpotential. Es kann sich somit kein Stromfluß vom Operationsfeld zur Erde ausbilden.



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Dieses Prinzip der Verwendung von bipolar ausgebildeten Elektroden in Verbindung mit einem erdschlußfreien,
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haben im Bereich der Gynäkologie
HIRSCH und ROOS zur laparoskopischen Tubensterilisation und MELCHIOR
für die Blutstillung durch bipolare
Mikrokoagulation beschrieben.

Am urologischen Resektoskop können Neutralelektrode und Aktivelektrode konstruktiv zu einer bipolaren Elektrode vereinigt werden, indem die Neutralelektrode — wie die Bilder 6 und 7 zeigen — als Metallplatte der Schneideschlinge aufgesetzt wird.

Diese Konstruktion als bipolare Elektrode bietet operationstechnisch jedoch einige Schwierigkeiten: Durch die Anordnung des großflächigen Metallplättchens oberhalb der Schneideschlinge werden offensichtlich die Strömungsverhältnisse gestört, so daß durch Blasenbildungen im Spülwasser die Sicht auf das Operationsfeld stark beeinträchtigt wird. Dieses Problem ist jedoch möglicherweise von einem erfahrenen Resektoskophersteller zu lösen.

Eine zweite Möglichkeit, die Neutralelektrode als Metallring in das blasennahe Ende des Resektoskopschaftes einzubauen (Bilder 8 und 9), hat sich dagegen operationstechnisch als problemlos erwiesen und gut bewährt.

Schon Messungen am Phantom haben gezeigt, daß sowohl bei Verwendung der bipolaren wie der Ringelektrode durch die neuartige Stromführung sehr saubere elektrische Verhältnisse geschaffen werden. Der Resektoskopschaft und das ihm anliegende Gewebe unterliegen keiner Belastung durch Leckströme, der Organismus ist — mit Ausnahme des kleinen Bezirkes zwischen den beiden Elektroden — nicht in den Stromkreis eingeschaltet, abernerende Ströme können nur in minimaler Stärke abgeleitet bzw. gemessen werden

Wir haben ein herkömmliches Resektoskop mit einem derartigen, die Neutralelektrode tragenden Resektoskopschaft, wie ihn die Bilder 8 und 9 zeigen, versehen und die normale Schneide-

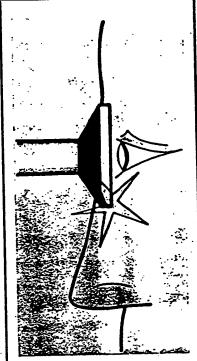
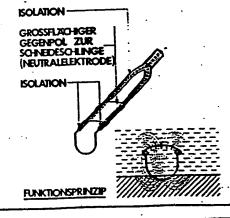


Bild 8: Verbrennungsgelahr im Gesicht des Operateurs: Bei isoliertem Endoskopschaft fließt der Leckstrom nicht über die Harmöhre des Kranken ab, er sucht sich den Weg zur Erde über den Operateur.

schlinge dieses Resektoskopes wie auch die Neutralelektrode an ein von der Firma Martin*) zur Verfügung gestelltes, an die besonderen elektrischen Verhält-

Bild 8: Bipolare Elektroden-Anordnung zum Schneiden bei transurethraler Resektion: Der Strom fließt von der Schneideschlinge direkt zu der nahen schlidförmigen Neutralelektrode.

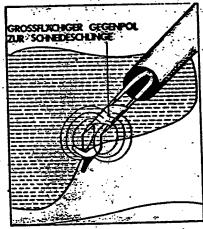


nisse angepaßtes HF-Chirurgiegerät mit "floating output" angeschlossen.

Mit diesem, von uns selbst derart modifizierten Instrument (Bilder 8 und 9) haben wir bis jetzt insgesamt 27 Elektroresektionen der Prostata und fünf der Harnblase komplikationslos ausgeführt. Die Schneidefähigkeit der Schlinge war durch die neue Stromführung in keiner Weise beeinträchtigt: Es lassen sich mindestens ebenso gut wie mit den herkömmlichen Instrumenten mühelos glatte, schorffreie Schnitte ausführen.

Dasselbe gilt für die Blutstillung, die mit der Koagulationselektrode ausgezeichnet gelingt.

Zur Prüfung der neuen elektrischen Verhältnisse haben wir bei fünf der insgesamt 32 Operierten elektrische Messungen durchgeführt. Die Anordnung der Meßinstrumente und die Meß-Strecken sind in Bild 10 wiedergegeben:



Blid 7: Auf engen Raum eingeschränktes einktrisches Spennungsfeld bei Unterwasserschnitt mit einer bipolaren Schneideschlinge.

- I) = Ableitstrom vom Resektoskop zu einer am Oberschenkel fixierten Neutralelektrode (bei nichtisoliertem Schaft fließt dieser Ableitoder Leckstrom über die Harnröhre zur Neutralelektrode zurück).
- U₁ == Elektrische Spannung zwischen Resektoskop und der Neutralelektrode.

") Firma Gebrüder MARTIN, D-7200 Tuttlingen.

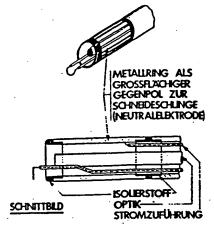
Asepsis im OP

Lautenschläger

STERILISIERAPPARATE UNVERB. ANGEBOT DURCH LAUTENSCHLÄGER 8192 GERETSRIED B. MÜNCHEN

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U₂ = Elektrische Spannung zwischen Resektoskop und Erde.



Blid 8: Bipolare Elektrodenanordnung zur trans urethralen Resektion: Die Neutraleiektrode ist als Metallring am Ende des Resektoskopschaftes angebracht.

13 = Ableitstrom vom Patienten zur Erde (Ursache von Verbrennungen des Patienten bei kleinflächigen Kontakten mit erdpotentialführenden, leitenden Op-Tisch-Teilen).

U₃ = Elektrische Spannung zwischen Patient und Erde.

Als MeBinstrumente wurden verwendet:

Strommesser Neuberger-Milliamperemeter mit Thermokreuz, Meßbereiche 0-150 mA u. 0--600 mA

messer

Spannungs- Kathodenstrahl-Oszillograph von Advance Electronics, Type OS 3000

Bei jedem zu Operierenden wurden die ersten Schnitte mit einem herkommlichen Resektoskop mit Teflonisolierung ausgeführt und dabei die während des Schneidevorganges auftretenden Leckströme und Spannungen gemessen. Abgeleitet wurde von den operateurnahen Metallteilen des Instrumentes.

Nach Erfassung der Meßdaten wurde das Instrument gewechselt und die



Bild 9: Photographie des Instrumentes aus Al bildung 8: Die Neutralelektrode sitzt als Metallring am Ende des Resektoskopschaftes,

Operation mit dem neuen, von uns modifizierten Resektoskop mit bipolarer Stromapplikation und erdschlußfreiem HF-Generator mit _floating output" durchgeführt.

Am gleichen Patienten wurden nunmehr unter den gleichen Bedingungen, bei unveränderter Lagerung die gleichen Messungen während des Schneidevorganges vorgenommen.

Die Tabelle zeigt das Mittel aus den gewonnenen Meßdaten, in der oberen Zeile bei herkömmlicher Technik, in der unteren Zeile mit dem neuen Instrument.

Der bei konventioneller Technik gemessene Leckstrom ist mit 150 mA so groß,



COLOSTOMIE-Beutel-Programm. Sicher, praktisch, hautschonend.

Bastisch, reibfest und

gleichmäßig haftend.

den Träger, auch bei

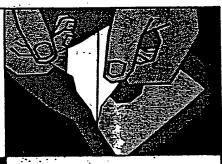
Absolute Sicherheit für

am Beutel haftet.

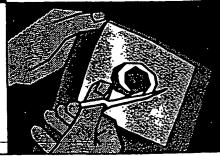
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MEDAS Osterrather Straße 7 5000 Köln. Tel 0221/52 05 39 Telex: 8 882 265 meda d





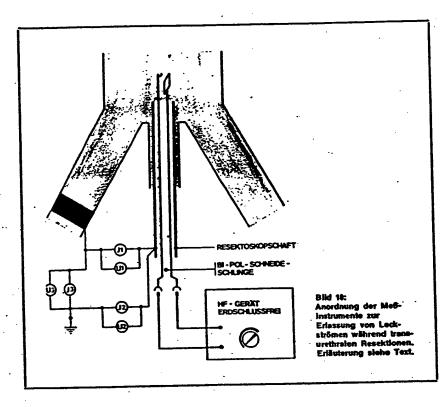
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Tabelle: MeBdaten, Schaltung siehe Bild 10

Operationstechnik	h	. Uı	l ₂ .	U ₂	-13	U ₃
konventionell, mit geerdeter Neu- tralelektrode	150 mA		chlossen — geerdet		entfällt, kurzgesc	
neue bi-polare Technik	15 mA	20 V	15 mA	20 V	< 5 mA	< 10 v



Leastrome gemessen werden, die als Ursache von Stromverletzungen an Harnröhre oder Haut des Kranken in Frage kommen.

Literatur:

- [1] ELSASSER, E., ROOS, E., u. SCHMIEDT, E.: Leckstrom infolge kapazitiven Stromüberganges als Ursache von Harnröhrenstrikturen nach TUR, Verh, Ber, Deutsche Ges, Urol, 25. Tg. 1974 München, Springer Verlag Berlin — Heidelberg, 1975, p. 44—48.
- [2] HIRSCH, HA., und ROOS, E.: Laparoskopische Tubensterilisation mit einer neuen Bikoagulationszange, Geburtsh., u. Frauenheilk, 34, 340-344 (1974).
- [3] MELCHIOR, H.: Bipolare Mikrokosgulation. Verh. Ber. Deutsch. Ges. Urol. 25. Tg. 1973 Aachen, Springer Verlag Berlin - Heidelberg 1974, p. 144-145.

Keywords:

Leckstromfreie transurethrale Resektion - neues Instrument

Transurethral resection without leakage of current — new instrument

Résection transuretrale sans fuite de courantnouveau appareil

Resección transuretral sin luga de corriente - un nuevo instrumento-...

Anschrift der Verfasser: Priv.-Doz. Dr. E. Elsässer, Krankenhaus der Barmherzigen Brüder, Urologische Abteilung, Romanstraße 93, D-8000 München 19.

E. Roos, Ing. VDI, Fa. Gebr. Martin, D-7200 Tuttlingen.

daß an kleinflächigen Kontaktstellen mit geerdeten Leitern auf jeden Fall mit Verbrennungen gerechnet werden muß, gleichgültig wo dieser Kontakt entsteht: Im Bereich der Harnröhre oder der Haut des Kranken oder der Haut des Operateurs.

Die Meßwerte bei Anwendung der neuen bipolaren Technik liegen unterhalb des kritischen Bereiches, und sie lassen sich mit großer Wahrscheinlichkeit durch konstruktive Verbesserungen am Resektoskop und am Zuleitungskabel noch weiter reduzieren.

Zusammenfassung

Es wird über ein Resektoskop mit neuartiger Anordnung der Elektroden berichtet, das mit einem leckstromfreien Hochfrequenzstromkreis arbeitet. Bisher wurden damit 32 komplikationslose Resektionen ausgeführt.

Der Hochfrequenzstrom, der von einem erdschlußfreien Hochfrequenzgenerator mit schwebendem Ausgangskreis geliefert wird, fließt von der aktiven Schneideelektrode durch das zu schneidende Gewebe und das Spülwasser direkt zu der ringförmigen, am proximalen Ende des Resektoskopschaftes angebrachten Neutralelektrode. Der Stromfluß im Organismus bleibt auf das kleine Operationsgebiet innerhalb der Blase beschränkt. Da die Zuleitungen zu beiden Elektroden keine Spannung gegenüber dem Massepotential (Erdpotential) aufweisen, kann sich auch kein Stromfluß vom Operationsfeld zur Erde ausbilden. Entsprechend können bei der neuen Methode -- im Gegensatz zu den herkömmlichen - keine nennenswerten

Medizinal-Markt / Acta Medicotechnica

Unsere nächste Ausgabe hat "Technische Mittel in der Krankenoflege" Fachthema. Außerdem berichtet Prof. Dr. Max Anliker, Institut für Biomedizinische Technik der Universität Zürich und der ETHZ, über neue diagnostische Verfahren sowie über Geräte, die an seinem Institut entwickelt wurden.

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Translated title:

An instrument for transurethral resection without leakage of current

German titie:

Über ein Instrument zur leckstromfreien transurethralen Resektion

Authors:

Elsässer, E.; Roos, E.

Authors' affiliation:

Krankenhaus der Barmherzigen Brüder, Urologische Abtellung [Brothers of Charity Hospital, Department of Urology], Munich

Source:

Medizinal-Marks/Acta Medicotechnica, Vol. 24, No. 4, 1976. Pages 129-

134.

Urethral strictures, which should in all probability be regarded as the result of electrical injury to the urethra, occur not infrequently after transurethral electrosurgical operations, mostly resections of the prostate or bladder (ELSÄSSER, ROOS, SCHMIEDIT).

In all surgical interventions involving high-frequency alternating current, the organism of the patient becomes part of an electrical circuit. The high-frequency current delivered by the generator enters the organism at the punctiform cutting electrode and flows via paths (the details of which are unknown) to the large-area, passive neutral electrode, grounded inside the HF generator, and thus to ground potential (Figure 1).

ELECTROSURGICAL UNIT

TERMINAL FOR NEUTRAL ELECTRODS, GROWNING

OPERATING TABLE, CROUNDED

BURN FROM LOCALIZED CONTACT WITH THE OFERATING TABLE

Figure 2: Electroscryfeni circuit with conventional grounded neutral electrode. The high-frequency current in this case always flows from the active electrode to ground via the path of least resistance.

Immediately beneath the punctiform active electrode, the current, entering with high density, encounters the high electrical resistance of the tissue. According to JOULE's law: heat = current strength² x resistance x time, such high temperatures develop in the tissue under the active electrode that the tissue structure bursts owing to vaporization of the fluid in the tissue, producing the intended parting of the tissue. Because the current usually spreads in the tissue immediately, its density drops very quickly and the current is therefore tolerated without incident during its further progress through the organism to the neutral electrode.

According to the laws of electrophysics, current will always flow along the path of least resistance between potentials. Usually this path is offered in the form of the neutral electrode (Figure 1).



Lattle =

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If, however, the patient comes into contact with other grounded metal parts - the operating table, for example - the current can also flow from that point to ground, particularly if such points of contact with the operating table are very close to the operation site or if, as a result of improper attachment, the neutral electrode offers higher resistance to the current transfer. If such contact points with grounded conductors are small in area, the current density again becomes very high and can lead to burns (Figure 1).

This basic risk of unimended electrical injury to tissue away from the operation site is particularly high in the case of urological interventions, for the following three reasons:

- 1. Particularly high current applications are required for cutting and coagulation operations under water.
- Conventional resectoscopes, which are composed of current-carrying (cutting loop) and non-current-carrying metal parts, represent capacitors which also permit a capacitive transfer of the high-frequency current to the metal parts insulated from the current-carrying elements.

ELSASSER, ROOS and SCHMIEDT indicated in 1974 that about 20% of the high-frequency output delivered to the cutting loop is lost espacitively as so-called "leakage current" at the resectoscope shaft.

More recent and more extensive studies on a phantom (Roos) have shown that - with a secondary connection via the irrigation liquid - current can in addition pass from the custing loop to those parts of the resectoscope inundated with irrigation liquid (shaft and optical system). The resectoscope shaft is thus significantly charged, both capacitively as well as via the irrigation liquid (Figures 2, 3, and 4).

LOOP - DERIGATION LIQUID - SHAFT SHURT
TOGETHER YIELD THE TOTAL LEARAGE CURRENT
LOOP - SHAFT CAPACITANCE
OUTSLOWING LEARAGE CURRENT
RESECTOSCOPE SHAFT
CUITING LOOP

Plears & Carrest-flow distribution with movements transmission reaction.

Figure 3: Courent looding of the arches in the case of courendonal TUR by leakage currents. In addition to the expective leakage current, the current flows directly from the casting loop to those pasts of the resecutionpe projecting late the indication liquid.

HF UNIT

JI - CURRENT FLOW

CUTTING LOOP ------> NEUTRAL ELECTRODE

IEREGATION LEQUED
LOOP CAPACITANCE

JI - CURURINI FLOW

SHAPT - NEUTRAL ELECTRODE

Pigure 4: Equivalent circuit for Figures 3 and 3.

3. The sum of the leakage currents flows via the urethral tissue lying up against the shaft to the neutral electrode; this usually takes place unnoticed and without negative consequences, because the resectoscope shaft with its large surface represents a passive electrode. If for any reason (preexisting urethral stricture, gaps in the insulating lubricant film) the current transfer takes place preferentially - or even exclusively - to a small circumscribed point on the shaft, the excessive current density at this point can lead to electrothermal damage to the tissue. Due to the particular anatomical conditions in men - the majority of urological patients are of course men - the sum of all the leakage currents delivered to the urethra must also pass the root of the penis, before they can spread in the true pelvis, so that the urethra must necessarily be exposed to a particularly high current loading in the region of this constriction point, which under certain circumstances can no longer to be tolerated in some individuals.

To protect the urethra from this high current loading with possible electrothermal damage, resectoscopes have recently been built in which the shaft either consists entirely of a nonconductive material (Teflon*) or is insulated by covering it with a Teflon tube.

But the use of such resectoscopes is also not without risk. The nonconductive shaft of course prevents the passage of the leakage currents from the resectoscope shaft to the urethra, but not the capacitive charging of the metal parts located inside the shaft. Because the insulation prevents the equalizing of potential via the urethra and the neutral electrode, the leakage current seeks another path to ground. This path leads of necessity through the operator, who must be considered grounded over a resistance which is not very high due to his unavoidable body capacitance relative to ground potential. Unpleasant discharge phenomena in the operator's face, which can sometimes be dangerous, are the result (Figure 5). Localized discharges are also frequent at other points, for example, during contact between the operator's arms and the grounded armrests of the operating table.

Figure 5: Denger of herms to the operator's face: In the case of an invalated undercope shall, the leakage entired does not flow swept via the arcture of the patient, but steks a pathway to ground through the operator.

But the patient, too, can suffer electrical injuries. If it is necessary to insert the instrument deeply in the case of a relatively long penis, contact of the glans with the metal parts at the end of the Tellon shaft can - as in one of the authors' own cases - lead to circular burning around the measus externus. Particularly dangerous is the use of instruments with a Tellon-covered metal shaft. The slightest defects in the Tellon coating immediately become the site of intensive current transfer and thermoelectric injury to the urethra.

-3-

Following the apparent failure of efforts to contain leakage currents through insulation, the obvious alternative was to take the opposite approach, namely, to offer the high-frequency current a path to balance the potential difference that would be so short and offering such low resistance that aberrant currents or leakage currents do not even occur.

This is effected:

- 1. by moving the large-area, passive neutral electrode extremely close to the active cutting electrode, which permits a potential equalization between the two electrodes within the smallest possible space, namely within the operating zone, i.e. the bladder, without other tissue being included in the current path. The current flows directly from the cutting loop to the neutral electrode through the adjacent tissue to be cut and the irrigation liquid.
- by connecting both electrodes to a high-frequency generator with an ungrounded "floating output" circuit.

Because in the case of this ungrounded circuit none of the electrode lines carries ground potential, there is also no voltage in opposition to ground potential. No current can thus flow from the operating zone to ground.

This principle of the use of bipolar electrodes in conjunction with an ungrounded, floating high-frequency circuit has been described by HIRSCH and ROOS in the field of gynecology, for laparoscopic tabe sterilization, and by MELCHIOR for stanching the blood using bipolar microcoagulation.

In the urological resectoscope, the neutral electrode and active electrode can be structurally combined into a bipolar electrode by incorporating the neutral electrode - as Figures 6 and 7 show - as a metal plate over the cutting loop.

INSULATION

LANGE-AREA ANTHOLE TO THE CUITING LOOP PREVIEAL RESCENDED

PISULATION

OFERATING PRINCIPLE

Figure & Bipolar decired: arrangement for earing in the case of transmerchail resocious. The carrent flows from the catting hope stands on the nearly landfillers posteral decireds.

LARCE-AND ANTIPOLE TO THE CUTTING LOOP

Fleure 7: Electrical values field limited to a restricted area, during enting with a bipolar cutting loop under water-

However, this bipolar electrode arrangement presents certain difficulties from the point of view

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of operating technique: The arrangement of the metal plate above the cutting loop apparently disturbs the conditions of flow, so that the formation of bubbles in the irrigation liquid greatly impairs the view of the operating field. A skilled resectoscope manufacturer may, however, be able to resolve this problem.

A second possibility, the incorporation of the neutral electrode as a metal ring into the end of the resectoscope shaft near the bladder (Figures 8 and 9), has on the other hand been found to be without problems from the standpoint of operating technique and have proved successful.

METAL RING AS LARGE-AREA ANTIPOLE TO THE CUITING LOOP DEUTRAL ELECTRODES

SICTIONAL VIEW

INSULATING MATERIAL OFFICAL SYSTEM POWER STREET

Pipers St. Arrangement of hipsiar electrodes for transcendural resection. The neutral electrode is attached as a metal ring to the end of the resection pe shall.

Figure 9: Photograph of the Instrument from Figure 3. The neutral electrode is positioned as a metal ring at the and of the resectorage that.

Measurements on a phantom have already shown that the use of both the bipolar and the annular electrode yield very good electrical conditions due to the new current path. The resectoscope shaft and the tissue adjacent to it are not subject to loading from leakage currents, the organism (with the exception of the small area between the two electrodes) does not form part of the circuit, and aberrant currents can only be derived or measured in minimal strength.

We have provided a conventional resectoscope with a resectoscope shaft carrying the neutral electrode, like that shown in Figures 8 and 9, and connected the resectoscope's standard cutting loop and the neutral electrode to an HF surgical unit with floating output, adapted to the special electrical conditions and made available to us by the Martin company. [Footnote: Firms Gebrüder MARTIN [Martin Brothers], D-7200 Tuttlinges]

With this unit (Figures 8 and 9), which we modified ourselves as described above, we have to date performed a total of 27 prostate electroresections and 5 bladder electroresections, all without complications. The cutting capability of the loop was in no way impaired by the new current pathway. Smooth, clean-edged cuts can be executed effortlessly, at least as well as with conventional instruments.

The same is true for stanching of the blood, with the coagulation electrode achieving excellent results.

To test the new electrical conditions, we took measurements with five of the total of 32 patients. The layout of the measuring instruments and the measurement intervals are shown in Figure 10.

-5-

RESECTOSCOPE SHAFT

BITOLAR CUTTING LOOP

HE WALL UNGROUNDED

Figure 10: Arrangement of the measuring instruments for recording the leakage currents carried transacethras reactions, see ion for explanation.

- I₁ = Leakage current from the resectoscope to a neutral electrode fixed to the thigh (when the shaft is not insulated, this outflow or leakage current flows back via the weekna to the neutral electrode).
- U₁ = Electrical potential between the resectoscope and the neutral electrode.
- Leakage current from the resectoscope to ground (cause of frequent burns to the face of the operator)
- U₃ = Electrical potential between the resectoscope and ground.
- I₂ == Leakage current from the patient to ground (cause of burns to the patient in the case of small-surface contacts with conductive parts of the operating table carrying ground potential).
- U, = Electrical potential between patient and ground.

The following measuring instruments were used:

Current meter:

Neuberger milliammeter with thermal interface. Measurement range: 0-150 mA and 0-600 mA.

Voltage meter:

Cathode-ray oscilloscope from Advance Electronics, Type OS 3000.

In the case of each of the patients being operated on, the initial cuts were made with a conventional resectoscope with Tesion insulation, and the resulting leakage currents and voltages arising during the cutting operation were measured. The connection was made to metal parts of the instrument near the operator.

After recording the measurement data, the instrument was changed, and the operation was completed using the new resectoscope, as modified by us, with bipolar current application and ungrounded HF generator with floating output.

The same measurements were then taken during the cutting procedure on the same patient, under the same conditions, with the position unchanged.

The table shows the averages from the measurement data obtained, with the upper line showing the results for the conventional technique and the lower line those for the new instrument.

At 150 mA, the leakage current measured using the conventional technique is so large that burns must in any event be anticipated at small contact points with grounded conductors, no matter where this contact arises: in the patient's urethra or on the patient's skin or on the operator's skin.

The readings obtained during use of the new bipolar technique lie below the critical region, and they can probably be reduced still further by structural improvements in the resectoscope or in the feed cable.

Table: Messerment data for circuit diagram on Pipure 10

Operating technique	I,	и,	1,	U _l	Ļ	U,
Conventional with grounded neutral electrode	Sharted, both grounded Oukted, directly shorted					y shorted
	159 mA	>00 V				
New Mpoker technique	15 mA	> Y	15 mA	×	47 MA	40.7

Summary

This subject of the report is a resectoscope with a new arrangement of the electrodes, which operates with a high-frequency circuit having no leakage current. It has thus far been used to complete 32 resections without complications.

The high-frequency current, delivered by an ungrounded high-frequency generator with a floating output circuit, flows directly from the active cutting electrode, through the tissue to be cut and the irrigation liquid, to the annular neutral electrode at the proximal end of the resectoscope shaft. The current flow in the organism remains within the small operation zone, inside the bladder. Because the lines to the two electrodes exhibit no voltage above ground potential, no current can flow from the operation area to ground. As a result, with the new method - in contrast to the conventional one - no significant leakage currents can be measured which could cause electrical injuries to the patient's methra or skin.

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[1] ELSÄSSER, B., ROOS, E., and SCHMIEDT, E.: Leakage current resulting from capacitive current transfer as a cause of urethral strictures after TUR [in German]. Verh. Ber. Deutsche Ges. Urol., 26th meeting, Munich 1974. Springer Verlag Berlin - Heidelberg, 1975, 44-48.

[2] HIRSCH, H. A., and ROOS, E.: Laparoscopic tubal sterilization with a new bicoagulation device [in German]. Geburth. u. Frauenhellk. 34, 340-344 (1974).

[3] MELCHIOR; H.: Bipolar microcoagulation [in German]. Verh. Ber. Deutsche Ges. Urol., 25th meeting, Aachen 1973. Springer Verlag Berlin - Heidelberg, 1974, 144-45.

Keywords:

Transurethral resection without leakage of current - new instrument [in German, English, French and Spanish]

Authors' addresses: Priv.-Doz. Dr. E. Elsässer, Krankenhaus der Barmherzigen Brüder, Urologische Abteilung [Brothers of Charity Hospital, Department of Urology], Romanstrasse 93, D-8000 Munich 19 [Pederal Republic of Germany]

H. Roos, Ing. VDI, Fa. Gebr. Martin, D-7200 Tuttlingen [Federal Republic of Germany].

- 8 -

Washington, DC August 18, 1998

I, Eric Norman McMillan, an ATA (American Translators Association) accredited German to English translator, do hereby certify that the attached document is a true translation done by myself of the document in the German language likewise attached.

Emmune

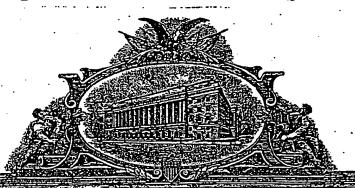
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Notary Public

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Certifying Officer

DEFENDANTS EXHIBIT DTX-312 require flushing of the region to be treated with normal saline, both to maintain an isotonic environment and to keep the field of viewing clear. The presence of saline, which is a highly conductive electrolyte, can cause shorting of the electrosurgical electrode in both monopolar and bipolar modes. Such shorting causes unnecessary heating in the treatment environment and can further cause non-specific tissue destruction.

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Present electrosurgical techniques used for tissue ablation also suffer from an inability to control the depth of necrosis in the tissue being treated. Most electrosurgical devices rely on creation of an electric arc between the treating electrode and the tissue being cut or ablated, causing the desired localized heating. Such arcs, however, often create very high temperatures causing a depth of necrosis greater than 500 µm, frequently greater than 800 µm, and sometimes as great as 1700 µm. The inability to control such depth of necrosis is a significant disadvantage in using electrosurgical techniques for tissue ablation, particularly in arthroscopic procedures for ablating and/or reshaping fibrocartilage, articular cartilage, meniscal tissue, and the like.

In an effort to overcome at least some of these limitations of electrosurgery, laser apparatus have been developed for use in arthroscopic and other procedures. Lasers do not suffer from electrical shorting in conductive environments, and certain types of lasers allow for very controlled cutting with limited depth of necrosis. Despite these advantages, laser devices suffer from their own set of deficiencies. In the first place, laser equipment can be very expensive because of the costs associated with the laser light sources. Moreover, those lasers which permit acceptable depths of necrosis (such as excimer lasers, erbium:YAG lasers, and the like) provide a very low volumetric ablation rate, which is a particular disadvantage in cutting and ablation of

A central aspect of the present invention is the ability of the probe 10 to deliver high energy flux levels effectively only to the intended areas, i.e., the target tissue, and not to surrounding healthy tissue or electrically conducting fluids (e.g., normal saline irrigant). Such directed energy transfer results in selective heating of the target tissue which allows the probe to cut, ablate or recontour the target tissue. Referring to Fig. 4, when the tip 12 of the probe 10 is pressed against a region of target tissue 80, some of the electrode terminals 50 will be in contact with target tissue, while other electrode terminals may be in contact with electrically conducting fluid 70. Each of the electrode terminals 50 experiences an electrical impedance which is characteristic of the material which is disposed between the individual electrode terminals 50 and the common electrode 54. The present invention takes advantage of the fact that the electrical resistivity of typical target tissue at frequencies of 50 kHz or greater (e.g., fibrocartilage and articular cartilage) is higher by a factor of approximately four or more than that of the surrounding electrically conducting fluid 70 typically used as an irrigant during arthroscopic and endoscopic procedures. Thus, if the current passing through each of the electrode terminals 50 is limited to a preselected maximum value, the regions of higher electrical resistance will generate more Joulian heating (power = I^2R , where I is the current through resistance, R) than a region of lower electrical resistance.

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In contrast to the present invention, electrosurgical methods and apparatus of the prior art involving a single electrode exhibit substantially reduced effectiveness when a portion of the exposed electrode is in contact with a low resistance pathway (e.g., normal saline irrigant). In those circumstances, the majority of power delivered from the single electrode tip is dissipated within the low resistance electrically

This appendix designation corresponds to a video admitted at trial as exhibit DTX – 315. DTX – 315 is reproduced on a CD-ROM located in a pocket envelope at the end of Volume 1 of this Appendix.

This range erroneously was used to refer to admitted exhibit DTX – 315. The proper designation for DTX – 315 is A19249.

This appendix designation corresponds to a video admitted at trial as exhibit DTX – 316. DTX – 316 is reproduced on a CD-ROM located in a pocket envelope at the end of Volume 1 of this Appendix.

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by which features the invention differentiates over the cited art, it should be mentioned that Applicant claims the combination of an endoscope as for instance shown in Fig. 1 with an electrosurgical device of the Fig. 2 embodiment, as previously elected. In this connection Applicant respectfully directs the Examiner's attention to Page 9, Lines 25 to 27 and Page 13, Lines 18 to 22. Applicant trusts that no new figure showing the electro-surgical device of Fig. 2 with the endoscope of Fig. 1 is required. Still furthermore, if a generic claim such as Claim 34 is ultimately held allowable, Applicant respectfully requests that Claims 51 to 53 specifically directed to the embodiment of Figs. 7 and 8 be allowed. At present, only Claims 34 to 50 and 54 to 56 read on the elected species of Fig. 2.

Claim 34 differentiates over the cited art by several features. First, at the tip of the endoscope an insulating projection (such as projection 18 in Fig. 1) is provided and the neutral electrode (11) is arranged at a distinct distance from the front edge of the insulating projection. The purpose of this arrangement is that material cut away by the treatment electrode (12) is kept away from the neutral electrode when the treatment electrode is retracted, for instance into the position shown in Fig. 1. If the insulating projection were not provided, there exists the danger that the removed material could short-circuit electrodes 11 and 12.

Secondly, the neutral electrode (11) must be mounted in the interior of the endoscope behind the front edge of the

- 6 -

S&N 0037007

insulating projection (18) so that it cannot come into contact with the tissue of the human body. This effect is described on Pages 15, 16 (however, in connection with the Fig. 7, 8 embodiment).

Thirdly, washing liquid (29) must be allowed to flow out of the endoscope so as to provide the necessary electrical conductor between the treatment electrode (12) and the neutral electrode (11). This washing liquid would form the resistor R (see Pig. 4). In this connection, the washing fluid would conduct electrical current just as the tissue fluid and the tissue itself of the human body.

The combination of the above features as recited in new claim 14 and the claims dependent thereon is not anticipated or even remotely suggested by the cited references.

Reference A does not disclose the feature of the washing fluid so that the indifferent electrode 24, 25, 26 has to project from the instrument. The disadvantage is that under certain conditions burning of the tissue at the electrode 26 can take place and that the current path between the indifferent electrode 26 and the active cutting electrode 22 is rather indefinite. A further disadvantage of the known instrument is that the indifferent electrode 24, 25, 26 is not insulated from the stem 10. Thus it is connected to earth potential. Thus the known instrument has all the disadvantages described in the introduction of the present application.

According to the concept of the present invention there is always a well-defined current path between the cutting

- 7 -

.S&N 0037008

electrode 12 and the neutral electrode 11 through the washing (and tissue) fluid. Since the neutral electrode does not contact the tissue there is no danger of an undesired burning of the tissue by the neutral electrode.

Reference B shows an instrument in which the cutting tool 12 carries two windings 1, 2 forming the two electrodes. Save for the very complicated structure of this tool there are high capacitive losses between the two windings. Purthermore it has turned out that burned tissue will collect on the bottom of the insulator 4 between adjacent wires 1, 2.

References C and D show instruments where both electrodes project from the distal end of the endoscope. Thus both electrodes come into contact with the tissue of the human body. Burning of the tissue will take place at both electrodes. In the present invention only one electrode, namely the cutting electrode 12 is burning the tissue whereas the neutral electrode does not influence or affect the tissue in any way.

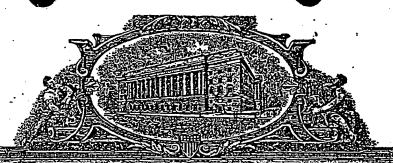
Reference E shows an insulating projection at the distal end of the endoscope. Furthermore obviously there is provided a washing fluid channel in the shaft of the endoscope. However the reference does not disclose the provision of a large-area neutral electrode at a certain distance from the front edge of the insulating projection.

The important feature of the invention that the cutting electrode as well as the neutral electrode are connected to the high frequency generator by conductors insulated from the shaft of the endoscope, is not disclosed in the reference. Also

- 8 -

Record of invention 10 Threwittelh ARTC 17713
HIGHLY CONFIDENTIAL
ATTORNEYS EYES ONLY DESENDANT EXHIBIT Z.D.IX

This appendix designation corresponds to a video admitted at trial as exhibit DTX – 897. DTX – 897 is reproduced on a CD-ROM located in a pocket envelope at the end of Volume 1 of this Appendix.



ARIOM WALLES CHANNES (CKANNING)

TO ALL TO WHOM THESE; PRESENTS; SHALL COME;

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office

December 12, 2002

THIS IS TO CERTIFY THAT ANNEXED IS A TRUE COPY FROM THE RECORDS OF THIS OFFICE OF THE FILE WRAPPER AND CONTENTS OF:

APPLICATION NUMBER: 09/098,205

FILING DATE: July 27, 1998

PATENT NUMBER: 6,224,592

ISSUE DATE: May 01, 2001

By

By Authority of the

COMMISSIONER OF PATENTS AND TRADEMARKS

P. R. GRANT Certifying Officer

PART (1) OF (2) PART(S)

DEENDANTS EXHIBIT DTX:3()04



UNITED STATES DEPARTMENT OF COMMERCE Patent and Trademark Office Address: COMMISSIONER OF PATENTS AND TRADEMARKS

Washington, D.C. 20231

ATTORNEY DOCKET NO. FIRST NAMED INVENTOR FILING DATE . APPLICATION NO. A-2-2 P 09/098,205 07/27/98 EGGERS EXAMPLE QM12/1115 021394 COHEN, L ARTHROCAPE CORPORATION PAPER NUMBER ART UNIT 595 N PASTORIA AVENUE SUNNYVALE CA 94086 3739 DATE MAILED: 11/15/99

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-800 (Rev. 2/8)

	Application No. 09/098,205	Applicantis	Eggers e	t all
Office Action Summary	Examiner Lee S. Coh	en .	Group Art Unit	
sponsive to communication(s) filed on Oct 28,	1999			•
is action is FINAL.	•			
nce this application is in condition for allowance accordance with the practice under Experte Or	<i>rayle,</i> 1935 C.D. 11; 453	U.G. 213.	•	
rtened statutory period for response to this acti ger, from the mailing date of this communicatio ation to become abandoned. (35 U.S.C. § 133 FR 1.136(a).	ion is set to expire	in the perio	70 100 100 PO PO	
sition of Claims				
Of the above, claim(s) 103-137		is/ere v	withdrawn from	consideration.
Clairn(s)	<u> </u>		is/are allowed.	•
Claim(s) 80-102			is/are rejected.	
Claim(s)		• •	is/are objected	to.
Claims	are subje	ct to restric	ction or election	requirement.
The drawing(s) filed on	er. Ecaminer. Eign priority under 35 U.S ED copies of the priority of the pr	.C. § 119(a locuments I)-(d). have been T Rule 17.2(e)).	•
ichment(s)				
Notice of References Cited, PTO-892	40 8		•	
Information Disclosure Statement(s), PTO-14	49, Paper Notst. <u>25</u>	-		
 Interview Summery, PTO-413 Notice of Draftsperson's Patent Drawing Rev 	dew. PTO-948		•	•
Notice of Informal Patent Application, PTO-1				
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SEE OFFICE	ACTION ON THE FOLLOW	NG PAGES -	.	
et and Textoneut Office 26 (Rev. 9-95)	Office Action Summary		Par	t of Paper No

Art Unit: 3739

Claims 103-137 stand withdrawn from further consideration by the examiner, 37

CFR 1.142(b) as being drawn to a non-elected invention. Election was made without traverse in Paper No. 6.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 83, 84, 87, 89-92, 94-96, 101, and 102 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 83, 84, 87, 89, and 94 - "the electrically conductive fluid" fails to accurately reference its antecedent. Claim 90 - "the probe" and "the distal tip of the probe" lack antecedent basis. Claim 101 - the inner member appears to be electrically connected to itself. Claim 102 - "the inner humen" lacks antecedent basis.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 3710 of this title before the invention thereof by the applicant for patent.

Claims 80-85, 88, 89, 92-96, and 98-102 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Baker (5,514,130). Applicant's attention is directed to column 8, lines 26-36.

Art Unit: 3739

Claims 80-84 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Knowlton (5,871,524). In Knowlton, the membrane is filled with electrolytic fluid. Electrodes 26 are positioned at various places in the membrane (col. 4, lines 57-64). The electrodes can be either monopolar or bipolar (col.5, lines 34-38). Therefore, when employing bipolar electrodes, a current path will be generated between the active and return electrodes of the bipolar electrode.

Claims 80-85, 92, 94-96, 98, and 99 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Abele (5,860,974). Applicant's attention is directed to column 6, lines 48-54 and column 8, lines 33-47.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be petented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the matter in which the invention was made.

Claim 87 is rejected under 35 U.S.C. 103(a) as being unpatentable over any of Knowlton, Baker, or Abele in view of Lax et al (5,569,242). The particular fluid for similar methodology is taught by Lax et al at column 7, lines 30-31. Accordingly, it would have been within the level of skill of the artisan to select saline to optimize performing the treatment:

Claim 97 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baker or Abele.

The particular voltage would have been within the level of skill of the artisan to select to optimize performing the treatment.

Art Unit: 3739-

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See Miller v. Eagle Mfg. Co., 151 U.S. 186 (1894); In re Ockert, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 80-83, 85-91, and 93 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-4, 7, 8, 10, 12, 19, 20, 38, and 40 of prior U.S. Patent No. 5,891,095. This is a double patenting rejection.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Orman, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.3210 may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Art Unit: 3739

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 84, 92, and 94-102 are rejected under the judicially created doctrine of double patenting over claims 1-64 of U. S. Patent No. 5,891,095 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: a method of applying electrical energy to a target site.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

The status of the applications referenced in the background of the invention should be updated and Attorney Docket numbers should be deleted.

Any inquiry concerning this communication should be directed to Lee S. Cohen at telephone number (703) 308-2998.

Lee Cohen Primary Examiner

	Notice of Refer	rences Cited	09/098.205 Examiner Lee S. C	Group Art		rage 1 of 1		
_			U.S. PATENT DOCUMENTS					
7	DOCUMENT NO.	DATE	. 84		CAASS	SURCLASS	ł	
1	5,860,974	1/1999	Al:	ode	606	41 .	4	
4	5,871,524	2/1999	Knor	witon	607	101	4	1
	5,891,095	4/1999	Egger	ns et al	604	114	4	.
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Notice of References Cited

PTO-892 (Rev. 9-95)

This correspondence is being deposited with the United Stat Postal Service as first class mail in an envelope addressed for Assistr—2 Commissioner for Patents	TO E JOJ
Washington, D.C. 20231 on	M 31 200 8
* Karin	THEN & TO ADD

Attorney Docket No. A-2-2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	•	•
PHILIP E. EGGERS et al.	Examiner: L. Cohen	
Application No.: 09/098,205) Art Unit: 3739)	LECHKC L
Filed: July 27, 1998) AMENDMENT	- 63. 13. 13.
For: SYSTEMS AND METHODS FOR ELECTROSURGICAL TISSUE TREATMENT IN CONDUCTIVE FLUID)))	EIVED 3 2000 CLH, ER 370
• .	•	ĕ

Assistant Commissioner for Patents Washington, D.C. 20231 .

Sir:

In response to the Office Action mailed November 15, 1999, please amend the above-identified application as follows.

IN THE SPECIFICATION:

On page 1, please delete the first paragraph (lines 8-21) and insert the

following:

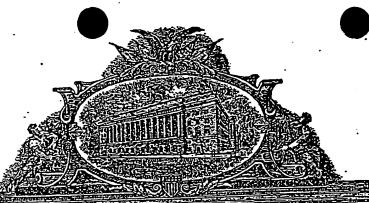
-The present invention is a continuation-in-part of Application No. 08/485,219,

filed June 7, 1995, now U.S. Patent No. 5,697,281, which is a continuation-in-part of Application No. 08/446,767 filed June 2, 1995, now U.S. Patent No. 5,697,909 which is a U.S. National Phase Filing of International Application No. PCT/US94/05168, filed May 10, 1994, which is a continuation-in-part of Application No. 08/059,681, filed May 10, 1993, now abandoned, which is a continuation-in-part of Application No. 07/958,977, filed October 9, 1992, now U.S. Patent No. 5,366,443, which is a continuation-in-part of Application No.

& division of Application the D81795, LBU, filed February 5, 1997, names. Pat. Ho. 5, 87, kg Which is a division of Application No. 081 361,958, filed Nov. 22,1895, now U.S. Pet No. 5,697,882, which is a

1. Philip E. Eggers et al. Serial No. 09/098,205 Page 2 07/817,575, filed January 7, 1992, now abandoned, the full disclosures of which are incorporated herein by reference. IN THE CLAIMS: Please cancel claim 82, amend claims 80, 81, 83, 90 and 99-102 and add new claims 138-159 as follows: (80. (Amended) A method for applying electrical energy to a target site on a body structure on or within a patient's body, the method comprising: positioning an electrode terminal into at least close proximity with the target sitein the presence of an electrically [conducting] conductive fluid; positioning a return electrode within the electrically [conducting] conductive fluid such that the return electrode is not in contact with the body structure to generate a current flow path between the electrode terminal and the return electrode; and applying a high frequency voltage difference between the electrode terminal and the return electrode such that an electrical current flows from the electrode terminal, through the region of the target site; and to the return electrode through the current flow path. ÷ 281. (Amended) The method of claim 30 wherein the electric current flows substantially through the electrically-[conducting] conductive fluid while minimizing electric current flow passing through the body structure. Ĭ, 82. Canceled 3 83: (Amended) The method of claim 80 further comprising immersing the target site within a volume of the electrically conductive fluid and positioning the return electrode within the volume of electrically conductive fluid to generate the current flow path between the [target site] electrode terminal and the return electrode. 1 90. (Amended) The method of claim 80, wherein the return electrode is located

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AD BRITAR OCKANAS (RABRADIANIA)

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UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office

December 12; 2002

THIS IS TO CERTIFY THAT ANNEXED IS A TRUE COPY FROM THE RECORDS OF THIS OFFICE OF THE FILE WRAPPER AND CONTENTS OF:

APPLICATION NUMBER: 09/098,205

FILING DATE: July 27, 1998
PATENT NUMBER: 6,224,592
ISSUE DATE: May 01, 2001

COMMISSION

By Authority of the COMMISSIONER OF PATENTS AND TRADEMARKS

P. R. GRANT
Certifying Officer

PART (1) OF (3) PART(S)



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on a distal end of an instrument shaft [the probe], further comprising an insulating matrix [at the distal tip of] on the probe between the return electrode and the electrode terminal, the insulating matrix comprising an inorganic material.

(Amended) The method of claim of wherein the electrode terminal is located on the distal end of a probe, and wherein the delivering step comprises supplying the electrically [conducting] conductive fluid to a proximal end of an axial lumen within the probe and directing the fluid through a distal end of the axial lumen to the electrode terminal

100. (Amended) The method of claim 84 further including positioning a distal end of a fluid supply shaft adjacent the electrode terminal, the delivering step comprising directing the electrically [conducting] conductive fluid through an inner lumen in the fluid supply shaft that is electrically connected to the return electrode and discharging the fluid through an open distal end of the supply shaft towards the electrode terminal.

Bot. (Amerided)) The method of claim [99] 34 wherein the electrode terminal is located on a distal end of a probe and the return electrode is an inner tubular member defining an axial lumen [electrically connected to the inner tubular member], the delivering step including directing/electrically [conducting] conductive fluid through the [inner] axial lumen to the distal end of the probe over the electrode terminal.

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102. (Amended) The method of claim 99 wherein the return electrode is an outer tubular member defining an axial passage between the outer surface of the probe and the inner surface of the outer tubular member, the delivering step including directing the electrically conducting fluid through the [inner lumen] axial passage to the distal end of the probe over the electrode terminal.

Please add the following new claims:

structure on or within a patient's body the method comprising:

contacting an active electrode with the body structure in the presence of an electrically conductive fluid;

spacing a return electrode away from the body structure in the presence of the electrically conductive fluid; and

applying a high frequency voltage difference between the electrode terminal and the return electrode such that an electrical current flows from the electrode terminal, through the electrically conductive fluid, and to the return electrode.

129. (New) The method of claim 138 wherein the electric current flows substantially through the electrically conductive fluid while minimizing electric current flow passing through the body structure.

140. (New): The method of claim 138 wherein at least a portion of the electric current passes through the body structure.

141. (New) The method of claim 138 further comprising immersing the target site within a volume of the electrically conductive fluid and positioning the return electrode within the volume of electrically conductive fluid to generate a current flow path between the electrode terminal and the return electrode.

17
1AZ. (New) The method of claim 138 further comprising delivering the electrically conductive fluid to the target site.

143. (New) The method of claim 138 wherein the electrode terminal comprises a single active electrode disposed near the distal end of an instrument shaft.

144. (New) The method of claim 138 wherein the electrode terminal includes an array of electrically isolated electrode terminals disposed near the distal end of an instrument shaft:

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2.

1.45. (New) The method of claim 138 wherein the electrically conductive fluid comprises isotonic saline.

649 649 146. (New) The method of claim 138 including independently controlling current flow to the electrode terminal based on electrical impedance between the electrode terminal and the return electrode.

147. (New) The method of claim 138 wherein the return electrode is spaced from the electrode terminal such that when the electrode terminal is brought adjacent a tissue structure immersed in electrically conductive fluid, the return electrode is spaced from the tissue structure and the electrically conductive fluid completes a conduction path between the electrode terminal and the return electrode.

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148. (New) The method of claim 138, wherein the return electrode is located on a distal end of a probe further comprising an insulating matrix at the distal tip of the probe between the return electrode and the electrode terminal, the insulating matrix comprising an inorganic material.

149. (New) The method of claim 148 wherein the inorganic material is selected from the group consisting essentially of ceramic, glass and glass/ceramic compositions.

547

150. (New) The method of claim 138 further comprising applying a sufficient voltage difference between the return electrode and the electrode terminal to effect the electrical breakdown of tissue in the immediate vicinity of the electrode terminal.

151. (New) The method of claim 138 further comprising measuring the temperature at the target site and limiting power delivery to the electrode terminal if the measured temperature exceeds a threshold value.

CX X 152. (New) The method of claim 138 further comprising applying a sufficient high frequency voltage difference to vaporize the electrically conductive fluid in a thin layer over at least a portion of the electrode terminal and to induce the discharge of energy to the target site in contact with the vapor layer.

183. (New) The method of claim 152 wherein at least a portion of the energy induced is in the form of pholons having a wavelength in the ultraviolet spectrum.

154. (New) The method of claim 152 wherein at least a portion of the energy is in the form of energetic electrons.

155. (New) The method of claim 138 wherein the voltage is in the range from 500 to 1400 volts peak to peak.

156. (New) The method of claim 138 further comprising generating a voltage gradient between the electrode terminal and tissue at the target site, the voltage gradient being sufficient to create an electric field that causes the breakdown of tissue through molecular dissociation or disintegration.

on the distal end of a probe, and wherein the delivering step comprises supplying the electrically conductive fluid to a proximal end of an axial lumen within the probe and directing the fluid through a distal end of the axial lumen to the electrode terminal

158. (New) The method of claim 138 further including positioning a distal end of a fluid supply shaft adjacent the electrode terminal, the delivering step comprising directing the electrically conductive fluid through an inner lumen in the fluid supply shaft that is electrically connected to the return electrode and discharging the fluid through an open distal end of the supply shaft towards the electrode terminal.

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159. (New) The method of claim 138 wherein the return electrode is an outer tubular member defining an axial passage between the outer surface of the probe and the inner surface of the outer tubular member, the delivering step including directing the electrically conductive fluid through the axial passage to the distal end of the probe over the electrode terminal.—

REMARKS

Claims 80, 81 and 83-159 are pending. Applicant has amended claims 80, 81, 83, 90 and 99-102 to address the Examiner's 112 rejections on page 2 of the Office Action. Applicant disagrees with the Examiner's double patenting rejections on pages 4 and 5 of the Office Action. However, to expedite prosecution, applicant has amended claim 80 to address the Examiner's double patenting rejection on page 4. In addition, applicant has submitted a terminal disclaimer concurrently with this response to obviate the obviousness-type double patenting rejection on page 5 of the Office Action.

The claims stand rejected as being anticipated or obvious over Baker, Knowlton, Abele and Lax. Applicant disagrees with these rejections. None of the cited references disclose or suggest the affirmative step of positioning a return electrode within electrically conductive fluid to generate a current flow path between the active and return electrodes, as is recited in claim 80. However, to expedite prosecution, applicant has amended independent claim 80 to even more clearly distinguish over the prior art. Claim 80 now recites the step of positioning a return electrode within the electrically conductive fluid such that the return electrode is not in contact with the body structure. Baker, Abele and Lax clearly do not disclose or suggest this step. As stated in col. 3, lines 58-63 and col. 6, lines 63-66 of Baker, the return electrode must function as a grounding pad and thus is in contact with the tissue. The ablation band is formed along the tissue between the two distal ends of the electrodes, which are both in contact with the tissue. In the Abele device, the electrodes are designed to press again the heart tissue with the desired contact pressure. Similarly, the Lax device must have contact between both the active and return electrodes and the patient's tissue.

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Philip E. Eggers et al. Serial No. 09/098,205 Page 8

In the Knowlton device, the thermal electrodes 26 are placed in a porous membrane 18, and an electrolytic solution 20 is introduced into the porous membrane to transfer RF current or power from RF electrodes 28 to the underlying collagen tissue (col. 5, lines 25-32). The monopolar mode is described (col. 5, lines 34-37) as having a return electrode in the form of a conductive pad applied to the patient's outer skin. The reference states that RF electrodes 26 can be monopolar or bipolar (line 33). However, the reference does not describe how a bipolar device would work to transfer the RF power to the underlying collagen tissue. For example, if electrodes 26 were both the active and return electrodes, the RF current or power would simply pass from one of the electrodes 26 through the conductive solution within membrane 18 to the other of the electrodes 26 (i.e., without transferring any RF power to the underlying tissue). Thus, even in the bipolar embodiment (which is not described), the return electrode must be in contact with the tissue in order for the RF power to be transferred thereto. Accordingly, applicant requests that this rejection be withdrawn.

New independent claim 138 recites the steps of contacting an active electrode with the body structure in the presence of an electrically conductive fluid, and spacing a return electrode away from the body structure in the presence of the electrically conductive fluid. None of the cited references disclose or suggest these two steps. In Baker, Lax and Abele, both active and return electrodes are in contact with the tissue. In Knowlton, the active electrode 26 is not in contact with the tissue.

Applicant believes that this application is now in condition for allowance. If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at (408) 736-0224.

Respectfully submitted,

John T. Raffle Reg. No. 38,585

ArthroCare Corporation 595 N. Pastoria Ave. Sunnyvale, California 94086 (408) 736-0224 FED -3 2000 FED -3 2000 Amendment

ArthroCare Corporatio 595 N. Pastoria Avenu Sumnyvale, CA 94086 (408) 736-0224
In re application of:
Application No.:

PHILIP E. EGGERS at al.

09/098,205

Filing Date:

July 27, 1998

Group Art Unit:

CONDUCTIVE FLUID

3739 FOR SYSTEMS AND METHODS FOR ELECTROSURGICAL TISSUE TREATMENT IN

I hereby certify that this is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

Assistant Commissioner for Patents Washington, D. C. 20231.

Atty. Docket No. A-.

THE ASSISTANT COMMISSIONER FOR PATENTS Washington, D.C. 20231

Transmitted here with is an amendment in the above-identified application.

- [] Enclosed is a petition to extend time to respond.
- [] Small entity status of this application under 37 CFR 1.9 and 1.27 has been established by a verified statement previously submitted.
- [] A verified statement to establish small entity status under 37 CFR 1.9 and 1.27 is enclosed.
- [] If any extension of time is needed, then this response should be considered a petition therefor.

The filing fee has been calculated as shown below:

OTHER THAN & (Cal. 2) SMALL ENTITY SMALL ENTITY Bana CLABAS HIGHEST NO. REMAINING PREVIOUSLY PRESENT RATE ADDIT. ADDIT. AFTER PAID FOR EXTRA FEE OR FEE AMENDMENT TOTAL MINUS X9--0 \$ XII-OR MINUS X39= =0 171t= [] FIRST PRESENTATION OF MULTIPLE DEP. CLAIM +130= 3 TOTAL TOTAL

If the entry in Col. 1 is less than the entry in Col. 2, write "0" in Col. 3.

If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, write "20" in this space.

If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, write "3" in this space. The "Highest Number Previously Paid For" (Total or Independent) is the highest number found from the equivalent box in Col. 1 of a prior amendment or the number of claims originally filed.

No fee is due.

Please charge Deposit Account No. 50-0359 as follows:

[]

Any additional fees associated with this paper or during the pendency of this application.

Extra copies of this sheet are enclosed.

John T. Raffle Reg. No.: 38,58;

ADDIT. FEE

GAU 3739

This correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed for Assistant Commissioner for Patents y estringion, D.C. 20231 Attorney Docket No. A-2-2 IN THE UNITED STATES PATENT AND TRADEMARK OFFICE In re application of: PHILIP E. EGGERS et al. Examiner: L. Cohen Art Unit: 3739 Application No.: 09/098,205 Filed: July 27, 1998 AMENDMENT For: SYSTEMS AND METHODS FOR **ELECTROSURGICAL TISSUE** TREATMENT IN CONDUCTIVE FLUID Assistant Commissioner for Patents Washington, D.C. 20231 Sir: In response to the Office Action mailed February 29, 2000, please amend the above-identified application as follows. IN THE CLAIMS: Please cancel claim 159 and amend claims 90, 102, 138, 141, 143, 144, 146-148, 150-152, 157 and 158 as follows: (Twice Amended) The method of claim 80, wherein the active return electrode is located on a distal end of an instrument shaft, further comprising an insulating matrix on the [probe] instrument shaft between the return electrode and the active electrode [terminal], the insulating matrix comprising an inorganic material.

[terminal] is located on the distal end of a probe, and wherein the delivering step comprises supplying the electrically conductive fluid to a proximal end of an axial lumen within the probe and directing the fluid through a distal end of the axial lumen to the active electrode [terminal].

end of a fluid supply shaft adjacent the active electrode [terminal], the delivering step comprising directing the electrically conductive fluid through an inner lumen in the fluid supply shaft that is electrically connected to the return electrode and discharging the fluid through an open distal end of the supply shaft towards the active electrode [terminal].

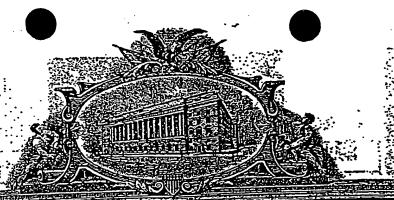
REMARKS

Claims 80, 81 and 83-158 are pending. Applicant has canceled claim 159 and amended claims 90, 102, 138, 141, 143, 144, 146-148, 150-152, 157 and 158 to address the Examiner's 112 rejections on page 3 of the Office Action.

The majority of the claims stand rejected as being anticipated by Roos and Mulier. Applicant disagrees with these rejections. The instant application discloses and claims, in part, novel methods for performing, and systems used to perform, electrosurgery in the presence of electrically conductive fluid. For example, in performing electrosurgery according to the method of claim 80, the active and return electrodes of the instrument are both positioned near a tissue site in the presence of electrically conductive fluid, such as isotonic saline or Ringer's lactate. The return electrode is spaced away from the tissue such that electric current flows from the active electrode, through the conductive fluid, to the return electrode.

Independent claims 80 and 138 each require that the return electrode be spaced from the tissue. Mulier does not disclose or suggest this feature. Mulier discloses a monopolar electrosurgery device that requires a return pad attached to the patient's skin.

Thus, the return electrode is always in contact with the tissue. Both electrodes 202 and 216 of the Mulier device are active electrodes that provide lesions in the tissue. Return electrodes are



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UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office

February 19, 2003

THIS IS TO CERTIFY THAT ANNEXED IS A TRUE COPY FROM THE RECORDS OF THIS OFFICE OF THE FILE WRAPPER AND CONTENTS OF:

APPLICATION NUMBER: 08/561,958
FILING DATE: November 22, 1995
PATENT NUMBER: 5,697,882
ISSUE DATE: December 16, 1997

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By Authority of the COMMISSIONER OF PATENTS AND TRADEMARKS

W.K. HAWKERS

Certifying Officer

DEFENDANTS EXHIBITE DIXS06

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PATENT APPLICATION

SYSTEM AND METHOD FOR ELECTROSURGICAL CUTTING AND ABLATION

· · Inventors: ·

Philip E. Eggers, a United States citizen residing at 5366 Reserve :: Drive, Dublin, OH 43017 and

Hira V. Thapliyal, a United States citizen residing at 1192 Volti Lane, Los Altos, California 94024

.Assignee

ArthroCare Corporation

Status:

Small Entity

TOWNSEND and TOWNSEND KHOURIE and CREW Steuart Street Tower, 20th Floor One Market Plaza San Francisco, California 94105 (415) 543-9600



Attorney Docket No. 16238-7

SYSTEM AND METHOD FOR ELECTROSURGICAL CUTTING AND ABLATION

BACKGROUND OF THE INVENTION

<u>Pield of the Invention</u>

The present invention relates generally to the field of electrosurgery and, more particularly, to surgical devices and methods which employ high frequency voltage to cut and ablate tissue.

The field of electrosurgery includes a number of loosely related surgical techniques which have in common the application of electrical energy to modify the structure or integrity of patient tissue. Electrosurgical procedures usually operate through the application of very high frequency currents to cut or ablate tissue structures, where the operation can be monopolar or bipolar. Monopolar techniques rely on external grounding of the patient, where the surgical device defines only a single electrode pole. Bipolar devices comprise both electrodes for the application of current between their surfaces.

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15. The method of claim 1 wherein the active electrode comprises an electrode array including a plurality of isolated electrode terminals.

- 16. The method of claim 1 wherein the electrically conducting fluid has a conductivity greater than 2 ms/cm.
- 17. The method of claim 2 wherein the electrically conductive liquid comprises isotonic saline.
- 18. The method of claim 4 wherein the electric field intensity is sufficient to cause molecular disintegration of tissue structure on the target site.
- 19. The method of claim 15 including independently controlling current flow from at least two of the electrode terminals based on impedance between the electrode terminal and the return electrode
- 20. The method of claim 15 wherein the return electrode is an outer tubular member, the shaft including an insulating member defining an axial passage between the insulating member and the outer tubular member, the directing step including directing the electrically conductive liquid through the inner lumen to the distal end of the shaft over the active electrode.
- 21. A method as in claim 15, further including maintaining a space between the electrode array and the body structure during the applying step.
- 22. The method of claim 21 wherein the maintain step comprises moving the electrode array transversely across the body structure.

23. A method for applying energy to a target site on a patient body structure comprising:

positioning an active electrode surface in close proximity to the target site in the presence of an electrically conducting liquid; and

applying a high frequency voltage between the active electrode surface and a return electrode surface, the high frequency voltage being sufficient to vaporize the liquid in a thin layer over at least a portion of the active electrode surface and induce the discharge of energy from the vapor layer.

24. The method of claim 23 wherein the active electrode surface comprises an electrode array including a plurality of isolated electrode terminals.

25. The method of claim 23 wherein the at least a portion of the energy induced from the vapor layer is in the form of photons having a wavelength in the ultraviolet spectrum.

- 26. The method of claim 23 wherein at least a portion of the energy induced from the vapor layer is in the form of energetic electrons.
 - 27. The method of claim 24 wherein the isolated electrode terminals each have a contact area below 15 mm².

26. The method of claim 24 wherein the isolated electrode terminals have circular contact surfaces with an area in the range from 0.01 mm² to 1 mm².

29. The method of claim 24 wherein the electrode sufface includes at least two electrode terminals.

30. The method of claim 24 wherein the electrode surface comprises between 4 to 50 electrode terminals.

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PATENT

Attorney Docket No. 16238-0007

IN THE UNITED STATES PATENT AND TRADEMARK

In re application of:

PHILIP E. EGGERS et al.

Application No.: 08/561,958

Filed: November 22, 1995

FOR: SYSTEM AND METHOD FOR ELECTROSURGICAL CUTTING AND) ABLATION

Examiner: M. Mendez

Art Unit: 3306

RESPONSE TO RESTRICTION REQUIREMENT AND AMENDMENT

Assistant Commissioner for Patents Washington, D.C. 20231

RECEIVED FEB 1 9 1997 **GROUP 3300**

Sir:

In response to the restriction requirement mailed January 7, 1997, please amend this application as follows.

IN THE CLAIMS:

Please amend claim 1, 23, 24, 29, 30, 43, 45, 48, 52, 54 and 55 as follows.

(Once Amended) A method for applying electrical energy to a target site\on a structure within a patient's body, the method comprising:

ive electrode and a return electrode providing an ag electrically coupled to a high frequency voltage source:

positioning/[an] the active electrode into at least close proximity with the target site in the presence of an electrically conducting liquid;

positioning (a) the teturn electrode within the electrically conducting liquid to generate a current flow path between the target site and the return electrode; and

	PATENT
	PHILIP E. EGGERS at al. Application No.: 08/561,958
	Page 2 applying high frequency voltage to the active electrode and the return electrode such that an electrical current flows
.///	and the return electrone such that the body structure in the from the active electrode, through the body structure in the
\mathcal{U}	region of the target side, and to the return electrode through
	the current flow path.
	July 31. (Once amended) A method for applying energy to a target site on a patient body structure comprising:
•	
	electrically coupled to a high frequency voltage source:
•	ll model oning [ah] the active electrode (surface) and
•	close proximity to the target site in the presence of an
	ll
	Il
([] and [a] bhe return electrode [surface], the
1 100	Il some maltage being sufficient to vaporize the inquite
5. / <i>//</i>	I least a dortion of the active electrons
	a thin layer over at least a find a state of energy from the vapor [surface] and induce the discharge of energy from the vapor
·	layer.
	24. (Once Amended) The method of claim 23 wherein the
	active electrode [surface] comprises an electrode array including
<u> </u>	a plurality of isolated electrode terminals.
ļ	
	29. (Once Amended) The method of claim 24 wherein the
	active electrode [surface] includes at least two electrode
	terminals.
\wedge 3	
	30. (Once Amended) The method of claim 24 wherein the
	active electrode [surface] comprises between 4 to 50 electrode
1	terminals.
1	(L. 6) 43. (Once Amended) The method of claim 23 wherein the
1 0/	July B 43. (Once Amended) The method of claim 23 wherein the active electrode [surface] and the return electrode [surface] are
at at	spaced apart by a distance in the range from 1 to 10 mm.
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<u> </u>	
	PHILIP E. EGGERS et al. Application No.: 08/561,958 Page 3
25	Silv 8145. (Once amended) The method of claim 23 wherein the active electrode (surface) and the return electrode comprise a bipolar array of isolated electrode terminals.
	(0 (0 - 1 - 1)) - (1 - 1)
Q°	48. (Once Amended) A method for applying energy to a target site on a patient body structure comprising: providing an active electrode and a return electrode electrically coupled to a high frequency voltage source: positioning (an) the active electrode (surface) in close proximity to the target site in the presence of an electrically conducting liquid; and applying a high frequency voltage between the active electrode (surface) and (a) the return electrode (surface), the high frequency voltage being sufficient to impart sufficient energy into the target site to ablate several cell layers of the body structure without causing substantial tissue necrosis beyond the several cell layers.
01	52. (Once Amended) A method for applying energy to a target site on a patient body structure comprising: providing an active electrode and a return electrode electrically coupled to a high frequency voltage source: positioning [an] the active electrode [surface] in close proximity to the target site in the presence of an electrically conducting liquid; and applying a high frequency voltage between the active electrode [surface] and [a] the return electrode [surface], the high frequency voltage being in the range from 600 to 1400 volts peak to peak.
Q8	54. (Once Amended) A method for applying energy to a target site on a patient body structure comprising: providing an active electrode electrically coupled to a high frequency voltage source: positioning [an] the active electrode [surface] in close proximity to the target site in the presence of an electrically conducting liquid; and

PHILIP E. EGGERS et al.
Application No.: 08/561,958
Page 4

PATENT

generating a voltage gradient between the active electrode [surface] and tissue at the target site, the voltage gradient being sufficient to create an electric field that breaks down the tissue through molecular dissociation.

55. (Once Amended) The method of claim 54 wherein the generating step comprises:

high frequency voltage sources

applying a high frequency voltage between the active
electrode [surface] and [a] the return electrode [surface]; and
vaporizing the electrically conducting liquid in a thin

layer over at least a portion of the active electrode surface.

REMARKS

The Examiner has restricted this application to one of the following inventions:

- (1) Claims 1-59, drawn to a method for applying electrical energy to a target site; and
- (2) Claims 60-79, drawn to an electrosurgical system for use with a high frequency power supply.

Applicant elects Group 1 without traverse. Applicant also notes that a divisional application directed to the Group 2 claims is being filed concurrently with this response.

Applicant has also made some minor claim amendments to some of the method claims in the elected group. These amendments have been made to more clearly define the relationship between the active and return electrodes and the high frequency voltage source.

Respectfully submitted,

John T Raffle Reg. No. 38,585

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, 8th Floor
San Francisco, California 94111-3834
(415) 326-2400
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I hereby cortify that this correspondence is being sent by facsimile transmission to: Examiner N. Mendez Fax No.: 1-703-308-0758
Assistant Commissioner for Patents,
Vashington, p.C. 20231,

PATENT

March 88, 1997

Attorney Docket No. 16238-000700

TOURISEID and TOURISEID and CREW LLP

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GROUP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

PHILIP E. EGGERS et al.

Examiner: MENDEZ, M.

Application No.: 08/561,958

Art Unit: 3306

Piled: November 22, 1995

Por: SYSTEM AND METHOD FOR)
ELECTROSURGICAL CUTTING AND)

SUPPLEMENTAL AMENDMENT

ABLATION

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

Before action on the merits, please amend the above identified application as follows.

P 30017 04/14/97 08561958

20-1430 030 204

130.00CH

IN THE SPECIFICATION:

On page 13, line 14, delete the word "using".

On page 18, line 27, delete "voltages" and insert -- voltage--.

On page 21, line 5, between *occurring* and *the region...* insert --in--, so that it reads --occurring in the region..-.

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PHILIP E. EGGERS et al. Application No.: 08/561,958 Page 2

PATENT

On page 22, line 36, delete "current" and insert ---

On page 23, line 12, delete the word "laser".

On page 32, line 31, insert --return-- before the word

IN THE CLAIMS:

Please cancel claims 1-22, 29, 30, 33, 36-38, and 57.

Please amend claims 23-28, 31, 32, 34, 35, 39-56, 58 and 59 as

follows. Please add claims 80-105. All claims have been set

forth for convenience of reference.

Please cancel claims 1-22.

(JS. (Twice Amended) A method for applying energy to a target site on a patient body structure comprising:

providing an [active] electrode terminal and a return electrode electrically coupled to a high frequency voltage source;

positioning the active electrode in close proximity to the target site in the presence of an electrically conducting terminal [liquid]; and

applying a high frequency voltage between the [active] electrode terminal and the return electrode, the high frequency voltage being sufficient to vaporize the fluid [liquid] in a thin layer over at least a portion of the [active] electrode terminal and to induce the discharge of energy to the target site in contact with [from] the vapor layer.

(Twice Amended) The method of claim 23 wherein the [active] electrode terminal comprises an electrode array including a plurality of isolated electrode terminals.

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	PHILIP E. EGGERS et al. Application No.: 08/561,958 Page 3
1 2 3 4 2 2 3 1 2 3	13 25. (Amended) The method of claim 25 wherein [the] at least a portion of the energy induced [from the vapor layer] is in the form of photons having a wavelength in the ultraviolet spectrum. 14 26. (Amended) The method of claim 25 wherein at least a portion of the energy [induced from the vapor layer] is in the form of energetic electrons. 3 27. (Amended) The method of claim 24 wherein the isolated electrode terminals each have a contact surface area in the range of about 0.25 mm² to 50.0 mm² [below 15 mm²].
3	28. (As Filed) The method of claim 24 wherein the isolated electrods terminals have circular contact surfaces with an area in the range from 0.01 mm ² to 1 mm ² . Please cancel claims 29 and 30. 5 32: (Amended) The method of claim 24 wherein the
$\frac{3^{3}}{5^{3}}$	electrode terminals are spaced from each other a distance of about 0,0005 to 2.0 [5 to 0.01] mm. 32. (As Filed) The method of claim 24 wherein the electrode
1 2 2 3	Please cancel claim 33. 34. (As Filed) The method of claim 24 wherein the electrode terminals comprise a material with a relatively low thermal conductivity. 35. (As Filed) The method of claim 14 wherein the electrode materials comprise a material selected from the group consisting of titanium, tungstem, platinum, aluminum and tantalum.
	Please cancel claims 36-38.

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	PATENT
· 11	PHILIP E. EGGERS et al.
	PHILIP B. Eddars et al. Application No.: 08/561,958
11_	Page 4 17 29. (Amended) The method of claim 23 wherein the high
	17 29. (Amended) The method of Claim
1	17 25. (Amended) The method of volts peak to peak. frequency voltage is at least 200 [300] volts peak to peak.
2	fraquency vorcage as
· 11	(Amended) The method of claim 23 wherein the
216	voltage is in the range from 500 [600] to 1400 volts peak to
BY 1 11	range is in the range from 500 [600] to 1400
J. 2	
3 ∦	peak.
	19 AT. (Amada) The method of claim 25 wherein the
	[active] electrode terminal is positioned between 0.02 to 5 mm
ant 1 11	alectrode terminal is positioned between
(10), 5	laceres site.
W 3	from the target site.
	20 A2. (Amended) The method of claim 23 wherein the
	20 12. (Amended) The until a 22 to 2 0 mm [10 to 400
n. (1	vapor layer has a thickness of about 0.02 to 2.0 mm [10 to 406]
3	micronsi.
	2) As. (Twice Amended) The method of claim 23 wherein
1	the distance between the most proximal portion of the [active]
, 2	the distance between the most province distal portion of the
Ala a	the <u>distance between the most province</u> in electrode <u>terminal</u> [surface] and the <u>most distal portion of the</u>
//Y 3	electrode terminal [surface] and the most urber by a distance] in return electrode is [surface are spaced apart by a distance] in
/ ✓ 4	the range from 0.5 [1] to 10 mm.
5	the range from Viz to
	(As Filed) The method of claim 24 wherein the return
	(As Filed) The section to the electrode array.
2	electrode has a distal end positioned proximal to the electrode array.
1_ ^	22/45. (Twice Amended) The method of claim 25 wherein
	2 245. (Twice Amended) The method of the
. 1	the [active] electrode terminal [surface] and the return
. 2	the [active] electrode terminal [surface] and the lactive are of comparable size and comprise a bipolar array of electrode are of comparable size and comprise a bipolar array of electrode are of comparable which both come in close proximity
1/1 3	electrode are of type which both come in close proximity
16/4	II
77' 5	I contact With the Body services
3	are desired to the
	23 46. (Amended) The method of claim 28 wherein the
1	13 the electrically conducting fluid [liquid] has a
/ 2	23 x6. (Amended) The method of the liquid liquid has a liquid phase of the electrically conducting fluid [liquid] has a
•	conductivity greater than 2 ms/cm.
	′ II
26 3	· harain the
BB 3	offer (Amended) The method of claim 23 wherein the
BB ;	(Amended) The method of claim 23 wherein the
•	Hearid phase of the electrically conductive Hills
	1 (Amended) The method of claim 28 wherein the 1 liquid phase of the electrically conductive fluid [liquid] comprises isotonic saline.

	PHILIP E. EGGERS et al. Application No.: 08/561,958
	Page 5 28 Mag. (Twice Amended) A method for applying energy to a
1	target site on a patient body structure comprising:
. 2	providing an [active] electrode terminal and a return
.3	electrods electrically coupled to a high frequency voltage
4	l i
. 5	source;
6	positioning the [active] electrode terminal in close
7	proximity to the target site in the presence of an electrically
19 8	conducting fluid [liquid]; and
12 9	applying a high frequency voltage between the [active]
10.	electrode terminal and the return electrode, the high frequency
11	voltage being sufficient to impart sufficient energy into the
12	target site to ablate [several cell layers of] the body structure
13	without causing substantial tissue necrosis below the surface of
14	the body structure underlying the ablated body structure [beyond
15	the several cell layers].
	3Z+28
	24 36 Amended) The method of claim 48 wherein the
2	applying step comprises:
3	vaporizing the electrically conducting fluid [liquid]
4	in a thin layer over at least a portion of the [active] electrods
· · s	terminal [surface]; and
6	inducing the discharge of photons to the target site in
ינ מי	contact with [from] the vapor layer.
$\mathcal{L}^{\prime \prime}$	24 to 24.
1)	(Amended) The method of claim As wherein the
. 2	applying step comprises:
3	vaporizing the electrically conducting fluid [liquid]
4	in a thin layer over at least a portion of the active electrode
5	surface; and
6	inducing the discharge of energetic electrons to the
7	target site in contact with [from] the vapor layer.
1	51. (As Filed) The method of claim 48 wherein the depth of
2	necrosis is 0 to 400 microns.
1 1	24 30 sz. (Twice Amended) A method for applying energy to a
Blf 2	target site on a patient body structure comprising:
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PATENT

PHILIP E. EGGERS et al. Application No.: 08/561,958 Page 6 providing an active electrode and a return electrode electrically coupled to a high frequency voltage source; 3 positioning the [active] electrode terminal in close 4 proximity to the target site in the presence of an electrically 5 6 conducting fluid (liquid); and applying a high frequency voltage between the [active] 7 electrode. terminal and the return electrode, the high frequency 8 voltage being in the range from 500 [600] to 1400 volts peak to 9 10 peak. 11 (As Filed) The method of claim 52 wherein the high frequency voltage is in the range from 700 to 900 volts peak to peak. 1 . 32 8754. (Twice Amended) A method for applying energy to a target site on a patient body structure comprising: 1 providing an active electrode electrically coupled to a 2 3 high frequency voltage source; positioning the [active] electrode terminal in close 4 proximity to the target site in the presence of an electrically 5 conducting fluid [liquid]; and generating a voltage gradient between the [active] electrode terminal and tissue at the target site, the voltage 8 gradient being sufficient to create an electric field that cause 9 the breakdown of [breaks down the] tissue through molecular **/**110 11 dissociation or disintegration. 12 · 33 5/7 55. (Twice Amended) The method of claim 54 wherein 1 the generating step comprises: providing a return electrode electrically coupled to a 2 3 high frequency voltage source; applying a high frequency voltage between the [active] 4 S electrode terminal and the return electrode; and vaporizing the electrically conducting fluid [liquid] 6 in a thin layer over at least a portion of the [active] electrode 7 8 terminal [surface].

	PATENT
. 1	DUTTITO B. EGGERS EC 41.
1	Application No.: 08/561,958
	Page /
1	14 56: (Amended) The method of claim 55 further
132	comprising developing a film layer of vapor between the active
// 3	electrode and the body structure [tissue] at the target site.
10	
	Please cancel claim 57.
レ	33.5%
	35 5 66. (Amended) The method of claim 53 further
1	comprising cooling the tissue with the electrically conducting
2	fluid [liquid] to reduce the temperature rise of those portions
3	fluid [liquid] to reduce the tracet gite [shield the tissue
4	of the body structure adjacent the target site [shield the tissue
ا کر	from the high frequency voltagel.
N14	
12"/1	Sg. (Amended) The method of claim Sg wherein the
2	cooling step includes translating the distal surface [tip] of the
3	electrode terminal [probe] over the target site to allow the
4	electrically conducting fluid [liquid] to contact the tissue
5	after the tissue has been subjected to the electric field [high
.6	frequency voltage].
	Please cancel claims 60-79, as they have been
	restricted out.
	185022666
	Please add claims 80-105.
L	Please and classes of the
	25 (New) The method of claim 22 wherein the
. 1	electrode height of the most distal portion of the electrode
2	terminal relative to the most proximal portion of the electrode
3	terminal relative to the most problem personal is in the terminal exposed to the electrically conducting fluid is in the
4.	terminal exposed to the electrically commercially
5	range from 0.0 to 2.0 mm.
M5	30 miles and a second or the
12 1	(New). The method of claims 23 and 46 wherein the
10	electrode terminal is surrounded and supported by an insulating
3.	matrix at or near the distal tip of the probe to electrically
4	isolate the proximal portion of the electrode terminal from the
5	electrically conductive fluid, the insulating matrix comprising
. 6	an inorganic material.
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PHILIP E. EGGERS et al.
Application No.: 08/561,958

PATENT

Page 8

(New) The method of claim all wherein the inorganic material is selected from the group consisting essentially of ceramic, glass and glass/ceramic compositions.

electrode height of the most distal portion of any of the electrode terminals relative to the most proximal portion of said electrode terminals exposed to the electrically conducting fluid is in the range from 0.0 to 2.0 mm.

electrode terminals are surrounded and supported by an insulating matrix at or near the distal tip of the probe to electrically isolate proximal portions of the electrode terminals from the electrically conductive fluid, the insulating matrix comprising an inorganic material.

/A

"95. (New) The method of claim 84 wherein the inorganic material is selected from the group consisting essentially of ceramic, glass and glass/ceramic compositions.

(New) The method of claim 82 wherein the distal surface of the electrode terminal is recessed below the surface of the insulating matrix by a distance from 0.01 mm to 1.0 mm.

(New) The method of claim 91 wherein the distal surface of the electrode terminal is flush with the surface of the insulating matrix.

electrode terminal comprises an electrode array including a plurality of isolated electrode terminals.

42 All (New) The method of claim \$8 wherein the generating step comprises:

providing a return electrode electrically coupled to a higher frequency voltage source;

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PHILIP B. EGGERS et al. Application No.: 08/561,958 Page 9

PATENT

applying a high frequency voltage between the return electrode and the array of electrode terminals; and vaporizing the electrically conducting fluid in a thin layer over one or more of the electrode terminals of the array.

(New) The method of claim 25 further comprising developing a film layer of vapor between one or more of the electrode terminals and the target site.

(New) The method of claim es further comprising cooling the tissue with the electrically conducting fluid to reduce the temperature rise of those portions of the body structure adjacent the target site.

of the energetic electrons is sufficient to cause disassociation or disintegration of molecules of the body structure.

(New) The method of claim 26 wherein the energy evolved by the energetic electrons is greater than 3eV.

45 36. (New) The method of claims 23 and 35 wherein the density of the vapor layer is less than about 1020 atoms/cm3.

electrode terminal is configured to promote bubble nucleation causing the formation of the vapor layer.

electrode terminal has a contact surface area in the range of.

about 0.25 mm² to 50 mm².

97: (New) The method of claims 48 and F7 wherein the high frequency voltage is at least 200 volts peak to peak.

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PATENT PHILIP E. EGGERS et al. Application No.: 08/561,958 Page 10 The method of claims 45 and 52 wherein the high frequency voltage is in the range from about 500 to 1400 volts peak to peak. Solfer The method of claims 45 and 52 wherein the (New) 95°. electrode terminal is positioned between 0.02 to 2.0 mm from the target site. 5\$ 26 ट्रा मध 100. (New) The method of claims 48 and 52 wherein the electrode terminal and the return electrodes comprise a bipolar array of isolated electrode terminals. 101. (New) The method of claims 25 and As further comprising cooling the tissue with the electrically conducting fluid to reduce the temperature rise of those portions of the body structure adjacent the target site. 42 25 23 -4 102. (New) The method of claim 10T wherein the cooling step includes translating the distal surface of the active electrode over the target site to allow the electrically conducting fluid to contact the tissue after the tissue has been subjected to the electric field. 5176 103. (New) The method of claims 23 and 48 further comprising evacuating fluid generated at the target site with a suction lumen having a distal end adjacent the electrode terminal. 104. (New) The method of claims 23 and 48 wherein the target site is a tumor within or on the patient's body. 28 32 . (New). The method of claims 46 and 52 wherein the electrode terminal comprises an electrode array including a

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plurality of isolated electrode terminals .--

HPR.25.1997 B: 35AH

> PHILIP E. EGGERS et al. Application No.: 08/561,958 Page 11

PATENT

REMARKS

Claims 23-105 are pending.

Applicants have cancelled claims 1-22 and 29, 30, 33, 36-38 and 57, and prepared a few minor amendments to the remainder of the claims. In addition, dependent claims 80-105 have been added to further claim the features of the present invention. Applicants note that these features are fully described in the present invention and no new matter has been

In view of the foregoing, Applicants believe all claims entered. now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at (415) 326-2400.

Respectfully submitted,

Reg./No. 38,589

TOWNSEND and TOWNSEND and CREW LLD Two Embarcadero Center, 8th Floor San Francisco, California 94111-3834 (415) 326-2400 Fax (415) 326-2422 JTR: TJS ENTENCHOONSON AND

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I hereby certify that his coins_condence is being deposited with the United States Postal Service as first class and in an envelope addressed the Commissioner of Patents and Tipdemarks. Washington, D.C. 20231, on 180, 17

PATENT

Attorney Docket. No. 16238-000700

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE APPROVED

In re Patent of:

PHILIP E. EGGERS et al.

01/14/390 EPOINT X 000000 X 57/18: 5,697,882

Issue Date: December 16, 1997

For: SYSTEM AND METHODS FOR SLECTROSURGICAL CUTTING AND ABLATION

FEB 1 2 1999

SINDICATER

REQUEST FOR CERTIFICATE OF CORRECTION UNDER 37 CFR \$1.323

Commissioner of Patents and Trademarks Washington, D.C. 20231

Sir:

Pursuant under 37 CFR \$1.323, Applicant submits a Certificate of Correction amending claim 23. These amendments to claim 23 have been made to correct typographical errors that were made in Applicant's Amendment filed on March 25, 1997. During that amendment, Applicant amended all of the claims to replace the term "liquid" with "fluid". In addition, Applicant amended all of the claims to replace the term "active electrode" with "electrode terminal".

In claim 23, however, Applicant mistakenly forgot to replace the term "active electrode" with "electrode terminal" on line 5. This term on line 5 derives antecedent basis from "an electrode terminal" on line 3 (also note the reference to electrode terminal on lines 7 and 9 of claim 23). Accordingly, in order to correct this error in antecedent basis, Applicant wishes to change "active electrode" on line 5 to "electrode terminal".

Patent No. 5,697,882 Philip E. Eggers et al. Page 2

Similarly, on line 6 of claim 23, Applicant replaced "liquid" with "terminal" instead of replacing it with "fluid" as in the rest of claim 23, and the rest of the claims. In particular, note line 8 of claim 23 which refers to the fluid, clearly deriving antecedent basis from an earlier recitation of "fluid" in the claim. This antecedent basis must come from line 6. In addition, note dependent claims 46 and 47, which also refer to the electrically conductive fluid. These claims depend from claim 23. Finally, Applicant points out that the rest of the independent claims in this application (claims 48, 52 and 54 were amended to recite the step of "positioning the electrode terminal in close proximity to the target site in the presence of an electrically conducting [liquid] fluid".

Accordingly, it should clearly be seen that the above - changes merely correct typographical errors made by the Applicant during prosecution of this case.

The desired corrections are set forth on form PTO 1050 enclosed herewith.

Enclosed is a check in the amount of \$100.00, pursuant to 37 CFR \$1.20(a).

Respectfully submitted,

John T. Raffle Reg. No. 38,585

ArthroCare Corporation 595 N. Pastoria Avenue Sunnyvale, California 94086 (408) 736-0224

UNITED STATES PATENT AND TRADEMARK OFFICE CERTIFICATE OF CORRECTION

PATENT NO. : 5,697,882

DATED: December 16, 1997
INVENTOR(S): Philip E. Eggers et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

IN THE CLAIMS:

23. A method for applying energy to a target site on a patient body structure

comprising:

providing an electrode terminal and a return electrode electrically coupled to a high frequency voltage source;

positioning the [active] electrode <u>terminal</u> in close proximity to the target site in the presence of an electrically conducting [terminal] <u>fluid</u>; and

applying a high frequency voltage between the electrode terminal and the return electrode, the high frequency voltage being sufficient to vaporize the fluid in a thin layer over at least a portion of the electrode terminal and to induce the discharge of energy to the target site in contact with the vapor layer.

Mailing address of sender:

Patent No. 5,697,882

No. of odd'l. copies

€ 500 per page

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John T. Raffle
ARTHROCARE CORPORATION
595 N. Pastoria Avenue
Sunnyvale, California 94086

PTO Form 1050 (modified); Atty Docket No.: 16238-000700

NOTICE RE: CERTIFICATES OF CORN :ON	. #k
DATE: 2-2-98 Mendez 3308	
10 : Supervisor, Art und	<u> </u>
SUBJECT: Certificate of Correction Request in Patent No. 569788	
A response to the following question(s) is requested with respect to the accompanying reque	est for a certificate of correction.
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Would the change(s) requested under 37 CFR 1.323 constitute new matter o	
2. Would the change(s) requested under 37 CFR 1.323 Materially affect the so by the examiner in the patent?	•
3. Applicant disagrees with change(s) initialed and dated by Examiner in lieu of the change request be granted?	of an Examiner's Amendment, Should
4. With respect to the change(s) requested, correcting Office errors, should the of correction?	patent read as shown in the certificate
5. If the amendment filed had been considered amendment have been entered?	by the Examiner, would the
PLEASE RESPOND WITHIN 7 DAYS AND RETURN THE FILE TO Room 918, P.	к <i>ш</i>
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TO: CERTIFICATE OF CORRECTION BRANCH	DATE:
The decision regarding the change(s) requested in the certificate of correction is she	own below.
Comments below	· ·
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4.YES UNO Comments below	•
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UNITED STATES PATENT AND TRADEMARK OFFICE CERTIFICATE OF CORRECTION

PATENT NO. : 5,697,882

DATED

: December 16, 1997

INVENTOR(S): Philip E. Eggers et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

52. The method of claims 23 or 48 further comprising cooling the tissue with the electrically conducting fluid to reduce the temperature rise of those portions of the body structure adjacent the target

54. The method of claims 23 or 48 further comprising evacuating fluid generated at the target site with a suction human having a distal end adjacent the electrode terminal.

55. The method of claims 23 or 48 wherein the target site is a tumor within or on the patient's

56. The method of claims 48 or 52 wherein the electrode terminal comprises an electrode array including a plurality of isolated electrode terminals.

Malling address of sender:

Patent No. 5,697,88

John T. Raffle ARTHROCARE CORPORATION 595 N. Pastoria Avenue Sunnyvale, California 94086

PTO Form 1050 (modified); Atty Docket No.: 16238-000700

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WHITED STATES PATENT AND TRADEMARK OFFICE

Patent

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: 5,697,536

Prior Examiner: Manuel Mendez

Date of New

: December 16, 1997

. Name of Patentee

: Eggers et al.

Title of Invention : SYSTEM AND METHOD FOR ELECTROSURGICAL

CUTTING AND ABLATION

REEXAMINATION REQUEST

Commissioner of Patents and Trademarks Box REEXAM Washington, D.C. 20231

CERTIFICATE UNDER 37 CFR 1.8: The Undersigned hereby certifies that this paper or papers, as described herein below, are being deposited with the United States Fostal Service, on the date shown below with sufficient poetage as first class mail in an envaderased to thei

Commissioner of Patents and Trade Don REPUM

Nashington, D.C. 20231
On this _23rd__ day of _December, 1999

Dear Sir:

660E21-109E00E

20005501

Reexamination is requested pursuant to 35 U.S.C. \$\$302-307 and 37 CFR \$1.510 of the above-identified patent. The following items are enclosed.

- Prior art relied upon and a Form PTO-1449 (37 CFR \$1.510 1. (b) (3)).
- A substantial new question of patentability raised by the 2. above prior art and the pertinency of the cited prior art of the claims for which reexamination is requested is set forth in the attached STATEMENT OF NEW QUESTION OF PATENTABILITY (37 CFR \$\$1.510 (b) (1) and (2)).
- 3. A cut-up copy of the original patent showing single columns of the patent reproduced on one side of a separate paper (37 CFR \$1.510 (b) (4)).
- The signature below certified that: .

A copy of this request and all accompanying papers has been served on the patent owner at the address provided for in 37 CFR \$1.33(c) by depositing the documents in an

envelope bearing first class postage in an official U.S. Postal Service repository at the date set forth below addressed as follows:

Name Hira V. Thapliyal Arthrocare Corporation Address 595 North Pastoria Avenue

Sunnyvale, California 94086

A check in the amount of \$2,520.00 is attached. 5. \$\$1.20(c) and 1.510(a)).

Please charge any deficiency to Deposit Account

Any refund should be made by check.

The name and address of the person making this request is:

Name William C. Fuess Reg. No. 30,054

FUESS & DAVIDENAS . . Address 10951 Sorrento Valley Road Suite II-G San Diego, CA

(858) 452-\$293 Tel. No.: Facsimile No. (858) 452-6035 E-mail: fuess@funtv.com

Please address all future correspondence as follows:

William C. Fuess FUESS & DAVIDENAS 10951 Sorrento Valley Road Suite II-G · San Diego, CA 92121-1613

Respectfully submitted,

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1999 December

William C. Fuess Reg. No. 30,054

STATEMENT OF NEW QUESTION OF PATENTABILITY

Patent and Claims for which Reexamination is Requested

Reexamination under 35 U.S.C. \$\$302-307 and 37 CFR \$1.510 is requested of U.S. Patent No. 5,697,536 which issued on December 16, 1997 to Eggers et al., and is assigned to Arthrocare Corporation (hereinafter "the Eggers '536 Patent"). Reexamination is requested of claims 1-3, 14, 16, 22, 27, 30, 33, 38, 41-48, 55, 57, 60 & 63, in view-of U.S. Patent No. 4,116,198 to Roos (hereinafter "the Roos '198 Patent"). It is noted that the Roos '198 Patent was not before the Examiner during the prosecution of the Eggers '536 Patent.

II. Statement of Substantial New Question of Patentability

A. Overview

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The Eggers '536 Patent is directed to devices employing high frequency voltage to cut and ablate tissue. (Eggers '536 1:19-21).

The Eggers '536 Patent discloses and claims electrosurgical devices that are designed and intended to be used in conductive fluids such as isotonic saline. The electrosurgical device generally includes a current supplying radio frequency generator; an active electrode, or an electrode terminal, mounted near the tip of a surgical probe; a return electrode positioned rearward of and in a spaced apart condition from said active electrode; an insulator separating the active and return electrodes; and, an

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UNITED STATE PARTMENT OF COMMERCE Patent and Trades k Office

Address: ASSISTANT COMMISSIONER FOR PATIENTS Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVEN	NTOR!	ATTORNEY DOCKET NO.
90/005,601	DECEMBER 30, 1999			16238-00610

ARTHROCARE CORPORATION 680 VAQUEROS AVENUE SUNNYVALE CA 94085-3523 EXAMINER

ART UNIT PAPER

MENDEZ, M. 13

DATE MAILED: NOVEMBER 15, 2002

Please find below and/or attached an Office communication concerning this application or proceeding.

SOUTH TOSKODOG

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Commissioner of Palents and Trademarks

cc: William C. Fuess, 3rd party. attorney

PTO-90C (Rev.3-96)

	Control No.	Patent Under	Reexaminati
	90/005,601		
Office Action in Ex Parte Reexamination	Examiner Manuel Mondez	Art Unit 3763	
•			
- The MAILING DATE of this communication app	ears on the cover sheet wi	th the correspondence a	ddress
Responsive to the communication(s) filed on 19 June 20		is made FINAL.	
A statement under 37 CFR 1.530 has not been received	from the patent owner.	•	
shortened statutory period for response to this action is set adure to respond within the period for response will result in ertificate in accordance with this action. 37 CFR 1.550(d). Ethe period for response specified above is less than thirty (3 kH be considered timely.	to expire a month(s) from the termination of the proceeding XTENSIONS OF TIME ARE	g and issuance of an exp GOVERNED BY 37 CFR	arte reccamin 1.550/cl.
THE FOLLOWING ATTACHMENT(S) ARE PART OF	THIS ACTION:		
1. Notice of References Cited by Examiner, PTO-8	32. 3. Interview	Summary, PTO-474,	
2. Information Disclosure Statement, PTO-1449.	4: See Con	dinustion Sheet.	
THE SUMMARY OF ACTION	•	•	
ta. 🛭 Claims 1-64 are subject to reexamination.		• •	
1b. Claims are not subject to recommender.			•
Ctaims have been canceled in the present	reexamination proceeding.		:
3. Claims are patentable and/or confirmed.	•	•	
G. 🖸 Claims 1-61 ere rejected.	•		
Claims are objected to.		•	
The drawings, filed on are acceptable.	<u>_:</u>		
7. The proposed drawing correction, filed on	•		•
Acknowledgment is made of the priority claim un		(().	
a) All b) Some* c) None of the cert 4□ have received.	Kied copies have	•	
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Application/Control Number: 90/005,601
Art Unit: 3763

DETAILED ACTION

Introduction

The prosecution of Reexamination No. 90/005,601 originated with the filing of a Reexamination Request on December 30, 1999. The Request indicated that the requester considered claims 1-3, 14, 16, 22, 27, 30, 33, 38, 41-48, 55, 57, 60, and 63, of Eggers, et al., U.S. Patent Number 5,697,536, referenced hereafter as Eggers '536, as being anticipated by Roos, U.S. Patent Number 4,116,198, referenced hereafter as Roos '198. After a complete review of the merits of the Request, the examiner of record concluded that Roos '198 raised a substantial question of patentability.

Consequently, an order granting the Request for Reexamination was mailed on February 2, 2000. The order was mailed for a second time on October 27, 2000.

The arguments presented by the Request concerning Roos '198 were addressed in a final decision by the examiner of record and reviewed by a board of primary examiners that convened to analyze the decision and make a final determination.

However, before the mailing of the written decision, a new Information Disclosure Statement (IDS) was timely received on June 19, 2002. The IDS comprises of evidentiary documents pertinent to pending litigation at the United States District Court

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in the State of Delaware (Arthrocare Suit-Delaware, USDC-D. DEL.-C.A. No. 01-504-

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In view of the new documents submitted by the IDS, the examiner of record has decided to divide this prosecution in two sections. The first section addresses the issues originally presented by the Request concerning Roos '198 and summarizes the patentability conclusion as it was decided by the examiner of record prior to the receipt of the new IDS. Finally, the second section addresses new relevant references as listed in the IDS received on June 19, 2002, and more specifically, the Supplemental Invalidity Response included in the submitted IDS package.

Section I: Analysis of the Roos Patent

After carefull consideration and review of Roos 198, it is hereby found that Roos 198 does not anticipate or render obvious any of the independent claims of record for a variety of reasons that will be discussed below.

Interpretation of the Preamble

The preamble of claim 1, discloses "an electrosurgical system for use with a high frequency power supply and an electrically conducting fluid supply". It is noted that whether a preamble constitutes a limitation to a claim is a matter to be determined by the facts of each case in view of the claimed invention as a whole. See, In re Stencel, 828 F.2d 751, 4 USPQ2d 1071, 1073 (Fed. Cir. 1987). Additionally, the preamble of a claim does not limit the scope of the claim when it merely states intended use of the invention. In re Pearson, 494 F.2d 1399, 1403, 181 USPQ 641, 644 (CCPA 1974).

Application/Control Number: 90/005,601

Art Unit: 3763

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Page 4

meaning to the invention claimed. Gerber Garment Technology, Inc. v. Lectra Syst., Inc., 916 F.2d 683, 688, 16 USPQ2d 1436, 1441 (Fed. Cir. 1990) (quoting) Perkins:

Elmer Corp. v. Computervision Corp., 732 F.2d 888, 896, 221 USPQ 669, 675 (Fed. Cir.), cert. Denled, 469 U.S. 857 (1984). Although no "litmus test" exists as to what effect should be accorded to terms appearing in a preamble, a patent application in its entirety should be reviewed to determined whether the inventors intended such language to represent additional limitations or mere introductory language. See, e.g., in re Paulsen, 30 F.3d 1475, 1479, 31 USPQ2d 1671, 1673-74 (Fed. Cir. 1994) (Citing Coming Glass Works v. Suitomo Elect, U.S.A., Inc., 868 F.2d 1251, 1257, 9 USPQ2d 1962, 1966 (Fed Cir. 1989).

Accordingly, a review of the specification in Eggers '536, reveals in column 4,

Accordingly, a review of the specification in Eggers '536, reveals in column 4, lines 63-67, that figure 1 is a perspective view of the electro surgical probe, an electrically conducting liquid supply and an electro surgical power supply. Electrically conducting liquid (50) is shown in figure 1 within an IV bag and in fluid communication with the electro surgical probe (10) as shown in figures 2A and 2B. Moreover, in column 12, lines 26-28, the specification states that electrically conducting liquid (50) (e.g., isotonic saline) is caused to flow along the fluid paths (83).

In view of the foregoing, the phrase "an electrically conducting fluid supply" in the preamble of claim 1, must be interpreted in view of the specification as a limitation disclosing a medical container (e.g., IV bag) that stores electrically conducting liquid

Application/Control Number: 90/005,601

Page 5

Art Unit: 3763

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(50) such as isotonic saline. The medical container is in fluid communication with the probe (10) allowing the electrically conducting liquid to make contact with the electrodes at the distal end of the probe (10). Additionally, in the last portion of claim 1, the phrase "the fluid path having an inlet adapted to be fluidly coupled to the electrically conductive fluid supply" unequivocally suggests that the drafter intended the preamble phrase "an electrically conducting fluid supply" to be a structural limitation. Clearly, the phrase "an electrically conducting fluid supply" gives life and meaning to the invention claimed, and therefore, must be considered in the assessment of patentability of claim 1.

Assessment of Patentability

The Roos '198 Patent never describes the use of "electrically conductive fluid" during electrosurgery. The Roos '198 Patent only discloses the use of an unspecified "washing liquid" that flows through the endoscope that houses the treatment and neutral electrodes. See Roos '198 Patent at 4:51-57, Fig. 1. The Roos '198 Patent does not state that the "washing liquid" that is supplied to the region of the surgical site is electrically conductive fluid. This omission is significant, because numerous non-conductive washing liquids, such as distilled water, glycine, sorbitol, and the like, have been used in electrosurgery and are still in use today. See, e.g., U.S. Patent No. 4,936,301 to Rexroth, et al. at 1:62-64 and 2:4-7.

In fact, the Roos '198 specification makes clear that the "washing liquid" delivered to the surgical site in the Roos '198 Patent is not electrically conductive. The

Application/Control Number: 90/005,601
Art Unit: 3763

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Roos '198 Palent states at column 6, lines 51-53 that "the neutral electrode 11 in the form of a steel band rests on the tissue in large area form, so that good electrical contact is ensured." If the "washing liquid" was electrically conductive, there would be no need for the neutral electrode to rest on the tissue in large area form to ensure good electrical contact. Electrical contact between the neutral electrode and the cutting electrode would be ensured by the "washing liquid" itself. The statement in the Roos '198 Palent that tissue contact with the neutral electrode is needed to ensure electrical contact plainty shows that the "washing liquid" described in the Roos '198 Palent could not have been electrically conductive.

A later-issued patent to the same named inventor, U.S. Patent No. 4,706,667, referenced hereafter as Roos ' 667, demonstrates unequivocally that the "washing liquid" disclosed in the Roos '198 Patent was not electrically conductive. The Roos '198 Patent claims priority to German Patent Application No. 2521719, referenced hereafter as "German Patent Application". The Roos '667 Patent explains at column 1 lines 14-29 that the device described in the German Patent Application (and thus in the Roos '198 Patent) did not work to cut tissue because the medium in contact with the electrodes was not electrically conductive:

"In a known electro-surgical high frequency cutting instrument of this kind (DE-OS No. 25 21 719) the neutral electrode is admittedly arranged in the immediate vicinity of the cutting electrode, it is however so separated from the tissue by a plastic cover, or

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Application/Control Number: 90/005,601 Art Unit: 3763

by its arrangement in an endoscope, that it can only enter into electrical contact with the cutting electrode electrolytically via the secretion which is present during the cutting process. As a result, it is difficult to maintain the current intensity required for trouble free cutting in a required precisely defined manner at the cutting electrode. Thus, if the power setting at the r.f. generator is too high, burns can result or, if the power setting is too low, then a poor cut or indeed injury occurs because the tissue to be cut sticks to the cutting electrode as a result of coagulation processes.

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According to the Roos '667 Patent, the device disclosed in the parent application to the Roos '198 Patent (and thus in the Roos '198 Patent itself) did not work because there was insufficient electrical contact between the neutral and cutting electrodes to cut tissue, even though the electrodes were in the "immediate vicinity" of one another. If the Roos '198 Patent had delivered electrically conducting fluid to the tissue site, such as isotonic saline, then the Roos '667 Patent surely would not have stated, as it did, that the cutting and neutral electrodes "only enter into electrical contact" with each other "via the secretion which is present during the cutting process." If Roos '198 had delivered electrically conducting fluid to the tissue site, there would have been an electrical connection between the cutting and neutral electrodes by virtue of the electrically conducting fluid itself, regardless of whether bodily secretions were present. Plainly, Roos '198 used non-conducting "washing liquid" and attempted to rely on bodily secretions from the cutting process to make the non-conductive "washing liquid" more

Application/Control Number: 90/005,601 Art Unit: 3763

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conductive. According to the Roos '667 Patent, these secretions did not make the non-conductive "washing liquid" electrically conductive.

Significantly, the Roos '667 Patent did not solve the electrical contact problem described in the Roos '198 Patent by introducing electrically conducting fluid to the tissue site. Rather, the Roos '667 Patent solved the problem of poor conductivity by disclosing a device in which both the cutting and neutral electrodes were in physical contact with the tissue so that current could flow from the cutting electrode, through the tissue, and to the return electrode, not through electrically conducting fluid. The Roos '667 Patent explains at column 4, line 30:

"The instrument is first of all placed in accordance with FIG. 1 onto the tissue 16

"The instrument is first of all placed in accordance with FIG. 1 onto the tissue 16 which is to be separated by means of a cut, with a concave ring-like contact surface 14 being formed between the tissue 16 and the neutral electrode 11 and with a very small funnel-like contact surface 15 being formed between the tip of the cutting electrode 12 and the tissue 16. If the r.f. generator is now switched on then an r.f. current indicated by the current lines 28 flows between the cutting electrode 12 and the neutral electrode 11".

In conclusion, because the Roos '198 Patent does not disclose or enable electrosurgical ablation in the presence of electrically conductive fluid, it cannot anticipate claims 1, 45, and 63, containing such an element. PPG Indus., Inc. v.

Application/Control Number: 90/005,601

Art Unit: 3763

Page 9

Guardian Indus, Corp., 75 F.3d 1558, 1566 (Fed. Cir. 1996) ("To anticipate a claim, a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter.").

Section II: References disclosed in the IDS dated June 19, 2002

Claim Rejections

In order to expedite the prosecution of this reexamination, the examiner of record will make direct references to the Supplemental Invalidity Response (Arthrocare Suit-Delaware, USDC-D. DEL.-C.A. No. 01-504-SLR) submitted with the IDS package dated June 19, 2002.

35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily



UNITED STATES DEPARTMENT OF COMMERCE Patent and Trademark Office Address: ASSISTANT COMMISSIONER FOR PATENTS

S: ASSISTANT COMMISSIONER FOR PATENTS

APPLICATION HOJ		FIRST NAMED INVENTOR! PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
90/005,601	DECEMBER 30, 1999	5,697,536	 16238-00610

ARTHROCARE CORPORATION
680 VAQUEROS AVENUE
SUNNYVALE, CA 94085-3523

Į.

EXAMINER

MENDEZ, M.

ART UNIT PAPER

3763 18

DATE MARLED: MARCH 14, 2003 AL

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

cc: William C. Fuess, 3rd party attorney

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PTO-90C (Rav.3-98)

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	Control No.	Patent Under Reexamination
Notice of Intent to Issue	90/005,601	·
Ex Parte Reexamination Certificate	Examiner	Art Unit
	Manuel Mendez	3763
- The MAILING DATE of this communication appears	on the cover sheet with the con	espondence address
1. 🔯 Prosecution on the merits is (or remains) closed in this e	x parte reexemination proceedin	g. This proceeding is subject to
reopening at the initiative of the Office or upon potition. Ct. 37 CF	R 1.313(e). A Certificate will be !	seved in view of
(a) Patent owner's communication(a) filed: 19 December	v 2002.	• 1
(b) Patent owner's late response Ned:		
(c) Patent owner's failure to file an appropriate respons	e to the Office action mailed:	
(d) Patent owner's failure to timely fie an Appeal Brief	137 CFR 1.192).	1
(e) Ciher	•	
Status of Ex Parte Reexamination:		
(f) Change in the Specification: Yes, No		
. (g) Change in the Drawing: Yes, No		1
(h) Status of the Claim(s): (1) Patent claim(s) confirmed: 1-64.	•	
(2) Patent claim(s) amended (including dependent o	n amended claim(s));	
(3) Patent claim(s) concelled:	•	
(4) Newly presented claim(s) patentiable:		
(5) Nowly presented concelled claims:		·
2. Mole the attached statement of reasons for patentability a	nd/or confirmation. Any comment	a considered necessary by
patent owner regarding reasons for patentability and/or co		
delays. Such submission(s) should be labeled: "Comment	s On Statement of Reasons for P	atentability and/or
Confirmation.* 3. Note attached NOTICE OF REFERENCES CITED (PTO-	000	
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4. Note attached LIST OF REFERENCES CITED (PTO-144		
5. The drawing correction request filed onkt:ap		
6. Acknowledgment is made of the priority claim under 35 U a) All b) Some* c) None of the certified o		ż
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* Certified copies not received: 7. Note attached Exeminer's Amendment.	()	
8. Note attached Interview Summary (PTO-474)		1.1
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Application/Control Number: 90/005,601 Art Unit: 3763

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Page 2

REEXAMINATION OF U.S. PATENT NUMBER 5,697,536

STATEMENT OF REASONS FOR PATENTABILITY ANDIOR CONFIRMATION

The following is an examiner's statement of reasons for patentability and/or . confirmation of the claims found patentable in this reexamination proceeding: The examiner of record concurs with the arguments presented by the patent owner on paper number 15. Accordingly, it is concluded that claims 1-64 are allowable over the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manuel Mendez whose telephone number is 703-308-2221. The examiner can normally be reached on 0730-1800 hrs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Brian Casler can be reached on 703-308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

> SUPERVISORY PATENT EYESTHER TECHNOLOGY CENTER STCO

March 4, 2003

Primary Examiner Art Unit 3763

ANGELA D. STRES SUPERVISORY PATENT EXAMINER

TECHNOLOGY CENTER 5700

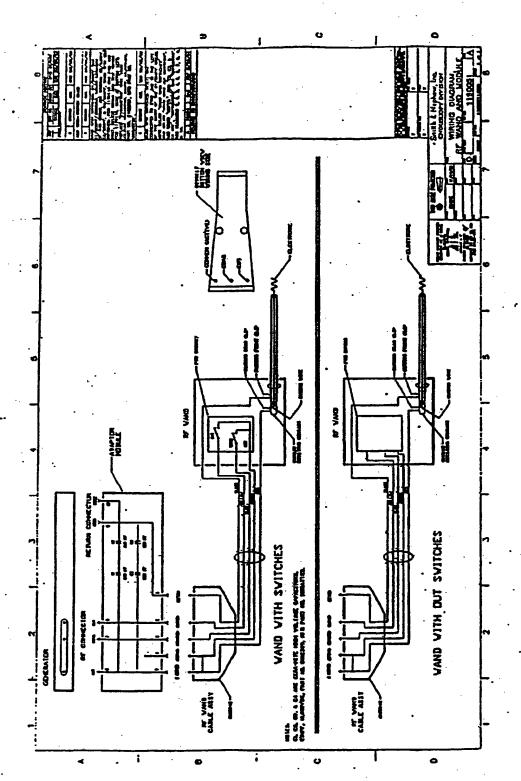
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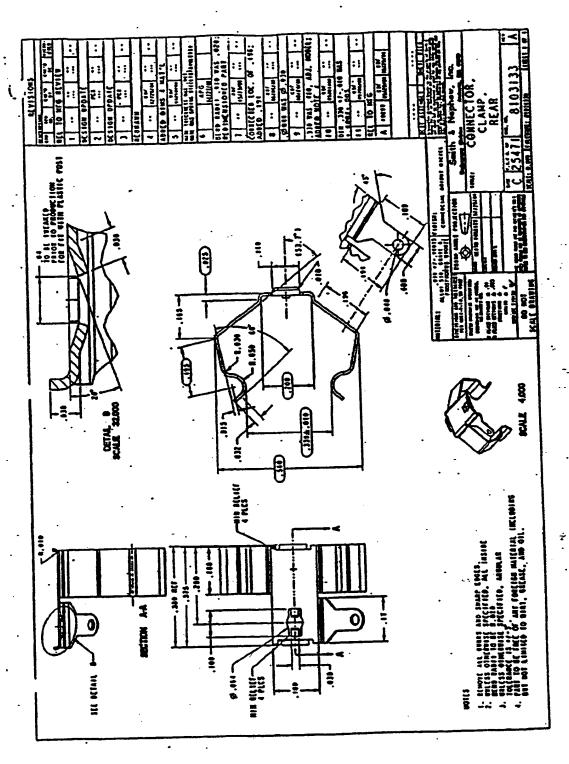
This appendix designation corresponds to a video admitted at trial as exhibit PX – 105. PX – 105 is reproduced on a CD-ROM located in a pocket envelope at the end of Volume 1 of this Appendix.



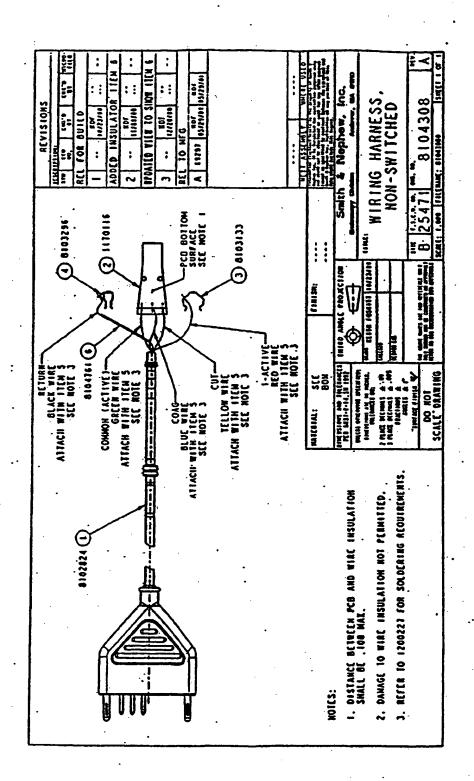
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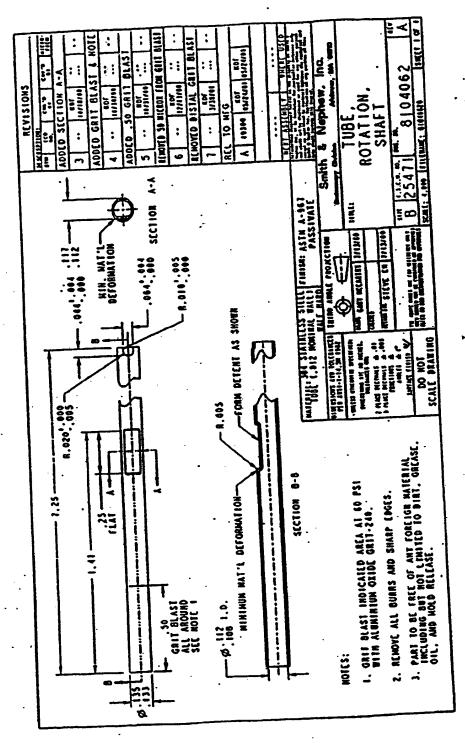
Plaintiff's Trial Exhibit PX 107A



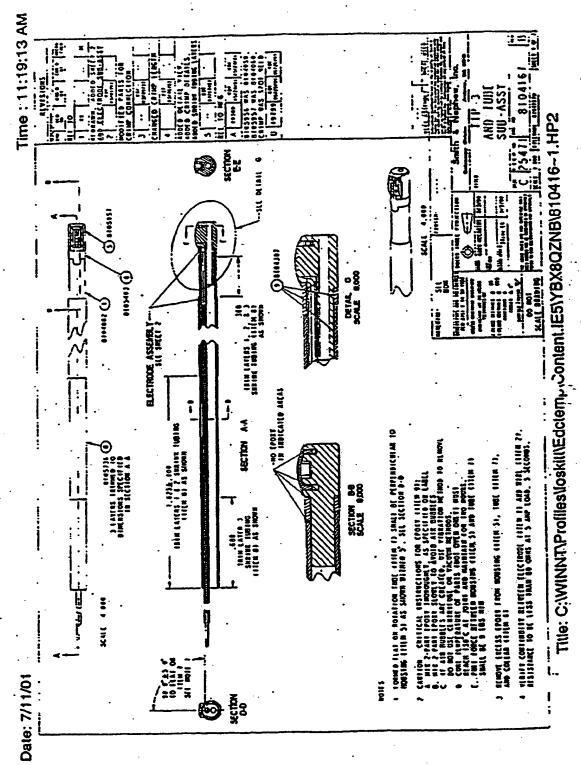




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Attorney's Eyes Only... HIGHLY CONFIDENTIAL

Dyonics® *Series 9000*ElectroBlade™ Resector

Instructions for Use



INDICATIONS

The Dyonics ElectroBlade Series 9000 Resector is indicated in arthroscopic surgical procedures of large and small articular cavities for resection and excision of soft tissues. The Dyonics ElectroBlade Resector is effective in tissue resection and hemostasis of bleeding vessels, it is intended for arthroscopic procedures using saline solution, Ringer's lactate, or other conductive solutions as an infigent under direct or video-assisted fiber optic visualization.

CONTRAINDICATIONS

- Use of the Dyonics ElectroBlade Resector is contraindicated in any non-arthroscopic surgical procedure and in procedures where salife and Ringer's factate is not used as an irrigent.
- The Dyonics ElectroBlade Resector is contraindicated in neurosurgery and cardiovascular surgery.
- The Dyonics ElectroBlade Resector is also contraindicated for use with generators not indicated in the instructions for Use.
- The Dyonics ElectroBlade Resector is not appropriate for patients for whom an arthroscopic procedure is contraindicated for any reason.
- Use of the Dyonics ElectroBlade Resector is contraindicated in patients with heart pacemakers or other electronic device implants.
- The Dyonics ElectroBlade Resector should not be used in patients exhibiting anlylosis, without adequate joint space or distention for arthroscopic inspection. Abrasion arthroplasty may not be effective in treating heavy patients or those with anlylosis, instability, or expectations beyond the relief of pain.
- Intracortical abrasion arthroplasty may be contraindicated in patients not qualifying for high tibial esteotomy or total knee conference.
- Synovectority is contraindicated when disease has progressed beyond the phase of synovial proliferation, and in cases of advanced rheumatoid arthritis when erosion of the articular cartilage is present.

IMPORTANT

- The Dyonics ElectroBlade Resector is competible with type "8" MDU (motor drive unit) and type "CF" Valleylab Electrosurgical Generators: Force FX", Force FX"-C, and Force 2.
- The Dyonics ElectroBlade Resector is preassembled, peckaged sterile and ready for use. Any attempt to disassemble the Dyonics ElectroBlade Resector cables will damage them and make them unusable.
- To remove a Dyonics ElectroBlade Resector from its sterile package, peel the Tyvek* seal off the blade tray. Sterility is guaranteed if peckage has not been opened or damaged.
- Do not put the electrosurgical generator on the Smith & Nephew shaver system cart.

READ THE DYONICS SHAVER SYSTEMS' OPERATIONS/ SERVICE MANUALS, THE GENERATOR MANUFACTURER'S OPERATIONS MANUAL, AND ANY ASSOCIATED EQUIPMENT OPERATIONS MANUALS FOR SYSTEM SETUP, OPERATION AND CLEANING INSTRUCTIONS.

WARNINGS

- Do not touch the open window area at the tip of the shaver blade whon power from the electrosurgical generator is being applied. Electrical injury may result.
- The Dyerics ElectroBlade Resector is offered as a single-use storile disposable device. Do not reuse. Attempts to reuse these devices may damage the insulative coating or cable resulting in harm to the patient or uses.
- De not activate the Dyonics ElectroBlade Resector when the tip is in contact with or in close preximity to a motal cannota. Aroling to a metal cannota may cause a patient bust.
- De not witheraw the Dyonics ElectroBlade Resector while power from the electrosurgical generator is being applied.
- Do not lay any electrosurgical instrument on the patient or drapes. If another electrosurgical instrument of any type, whether foot or hand controlled is activated, both devices will be activated and may result in patient burns.
- Failure of the RF surgical equipment could result in an unintended increase in power output.
- During RF activation, use arthrescopic visualization to ensure that suction is on and the shaver blade tip and the uninsulated tube return are completely surrounded by inigant solution.
 Ensure that there is an unintersupted flow of inigant through the hinds.
- Do not wrap the cables around metal objects. Wrapping the cable around metal objects may induce currents that could lead to shock, fires, or injury to the patient or surgical personnel.
- It is recommended that RF activation of the Dyonics
 ElectroBinde Resoctor be applied in brief intervals to minimize
 the potential for collatoral tissue damage associated with the
 use of RF energy.
- As with all electrosurgical devices, do not use in the presence of flammable anosthetics or oridizing gases, such as nitrous ended or exygen. An electrosurgical device has the potential for providing a source for ignition. Endogenous gases, which accumulate in body cavities, can also be a source of ignition.
- The electrode tip may remain not enough to cause burns after the electrosurgical current is deactivated.
- The patient should not come into contact with metal parts which are grounded or which have appreciable capacitance to ground (i.a., operating table supports). The use or anti-static sheeting is recommended for this purpose.

Plaintiff's Trial Exhibit PX 189

SN 0046676 ·

Dyonics® Series 9000 ElectroBlade™ Resector

Clinical Evaluation Summary

Prepared by:	. •	
Diana Orxivia	.31202	_
Dianne DeLucia	Date	•
Clinical Research Associate II	•	•
Reviewed by:	• *	
, <u> </u>	•	• • •
Paren Drucker	3-12-02	<u>.</u>
Karen Drucker	Date	
Project Leader	:	•
Juan K. Kann	3/11/02.	_
Uason Krieser	Date	• •
Domestic Market Manager	•	_
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Steve Keene	Date	100
International Market Manager	•	
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Tedd Gosian	Date	14/3/02
Clinical Research Manager	•	
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Dyonics © Series 9000 Electro BladeTM Resector Clinical Evaluation Summary Page. I

Plaintiff's Trial Exhibit PX 191

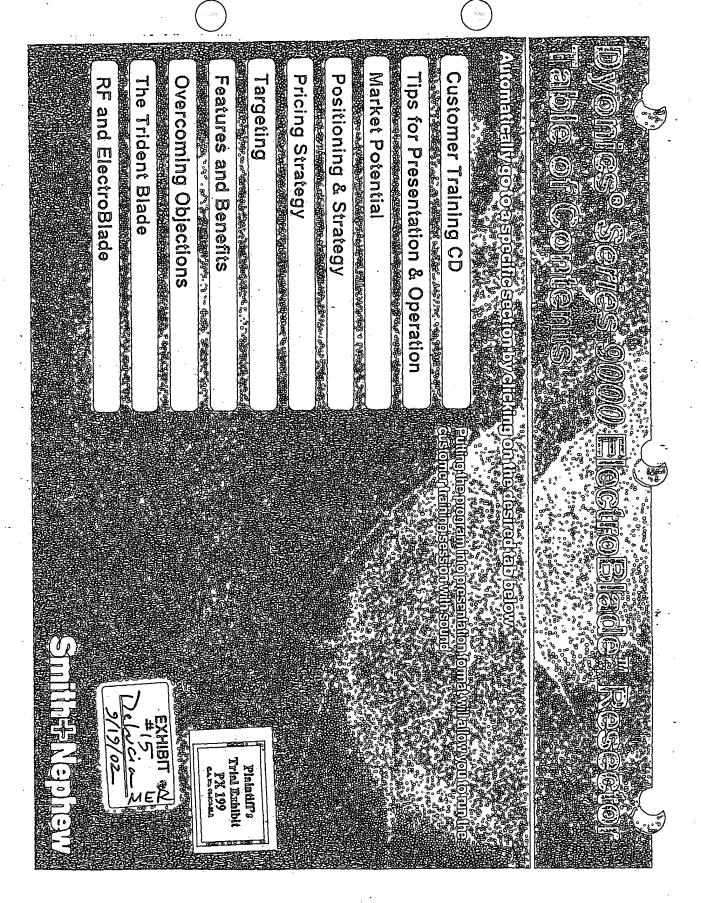
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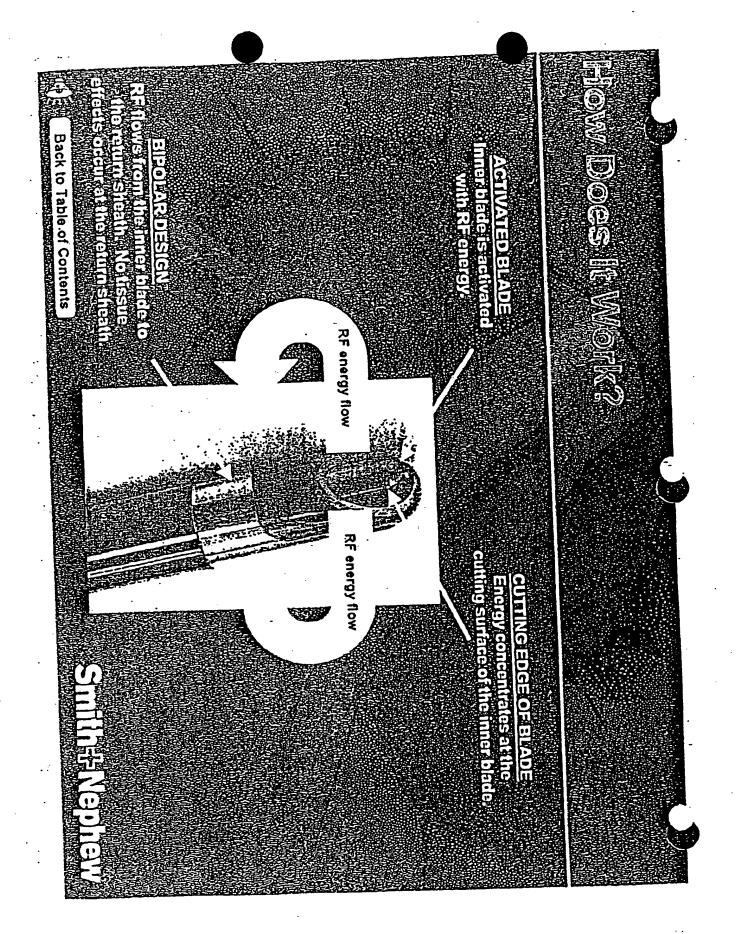
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Dyonics® Series 9000 ElectroBlade¹³¹ Resector Chincal Evaluation Summary Page 6 of 18





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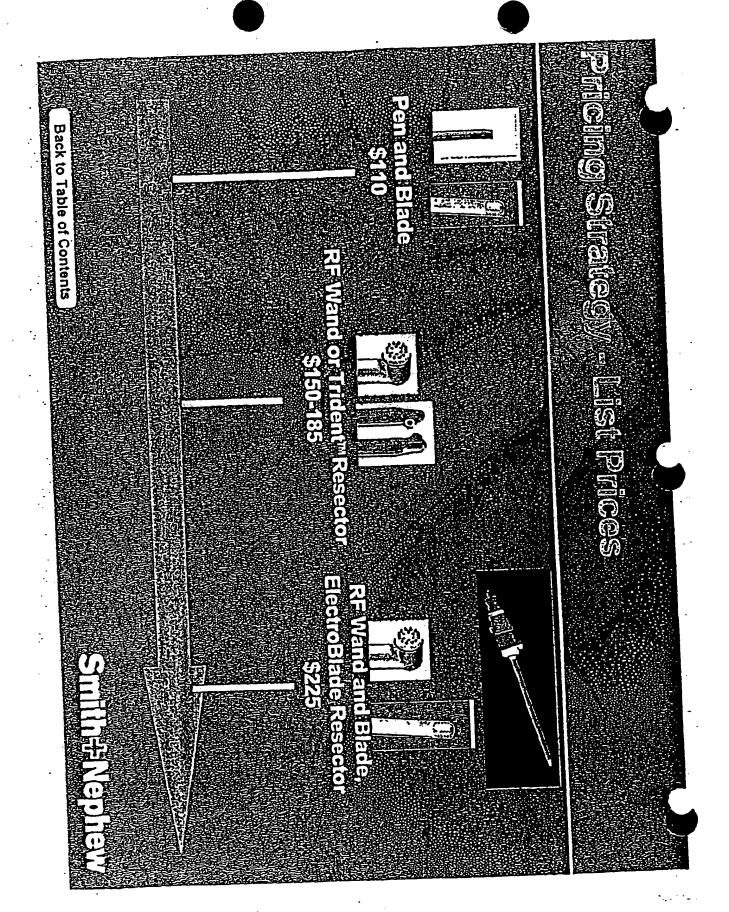
The ElectroBlade Reservors NOT designed to use RF energy to ablate

tissue - The ElectroBlade Resector removes tissue through mechanical resection and provides coagulation with RF. Do not present this product as an ablative device

Outer sheath edge - The outer sheath of the ElectroBlade Resector has an edge. Ensur your surgeons are aware of this edge so they are careful when using the blade near articular cartilage.

Ensure the entire the including the return is immersed in saline area in the men in is inactive because the energy is spread over a large surface area. If the shear is not completely immersed in saline, the area where the RF energy Jeums is reduced. This could allow the return to become an adversite when the RF is much one.

Back to Table of Contents



A 22659

- We used pricing of our key competitive products (blade and wand) to set our price
- The ElectoBlade Resector has completely unlove benefits that no other company can offer at this time.
- We are creating an entirely new productional of the spirits includes of the solu-us the and weater calibration of the Online estoning products of the
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PRIMARY VEGET PROGEDURE

Subactomial decompression - me ElectoBlade Resector should perform besuin

SADS The product is well suffection this procedure for the following reasons:

Traditional shaver blades tend to resect the loose itssue, such as the bursa, much faster than an ablat wand. This is because suction pulls the loose tissue into the blade where it is efficiently out. Wand of your surgeons moved to RF primarily to control the bleeding that a standard shaver blade can't do your surgeons moved to RF primarily to control the bleeding that a standard shaver blade can't do your surgeons moved to RF primarily to control the bleeding that a standard shaver blade can't do your surgeons moved to RF primarily to control the bleeding that a standard shaver blade can't do.

Many surgeons are concerned about removing the outsalvissue of of the joiator cult wheretablative ist energy could adversely impact viable lissue. The falcinoblade Reservoir desinotablate which should

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SECONDARY TARGET PROCEDURE: We have had success in clinicals in these procedures. However, the evaluations also demonstrated that the products penetration will be lower when compared to SAD's.

I OUT HOUS TESTATES OF SOURSE Where desing is an issue

WHAT TO AVOID—This product is not indicated for anticular cardiage sculpting of the mail capsular shunkage. Do not sell the ElectroBlade Resector as an ablative product of must ensure that your suggeon understands that the product is designed for mechanical resection and the RF componential uses for simultaneous coagulation, not

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Terger Products in the O.R.

Target disposable resection devices—Your primary larget should be surgeons with the ablade and a wand in a single procedure. In this case, the ElectroBlade Resector may not have a significant cost pairlet and can provide the benefit of reduced insertion and removal of

Shaver Tinese suggeons should be able to leasify control resection and IXE coagulation with too toe of simultaneously suggeons using the too control for the shaver will have to operation pedalisating same time to use the simultaneousliesed to have to operation pedalisating same time to use the simultaneousliesed to have coagulation seather.

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Selling Rif Weines and the Dyonics

In a specific account some of your surgeons may prefer the ElectroBlade Resector while others will continue to use standard RF. In addition, the ElectroBlade Resector is not indicated for shrinkage or articular cartilage

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Smith[⊕]Nephew

Instructions for Use Dyonics^o Series 7000 RF Arthroscopic Probe

DESCRIPTION

The Dyopics Series 7000 RF Arthroscopic Probe is designed for arthroscopic surgical procedures of the knee, shoulder, anide, ebow, wrist, and hip. The device consists of a sterile, single-use bipolar probe with suction control, a connector cable and optional hand controls (Figure 1). It is designed for use with a non-sterile, reusable Dyonics Control RF Generator Adaptor. The adaptor and probe are designed for use together as a single unit and plugged into an electrosurgical generator.

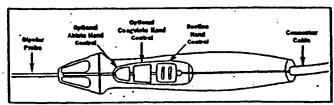


Figure 1. Dyonics Sedes 7000 RF Arthroscopic Probe with optional hand controls.

INDICATIONS

The Dyonics Series 7000 RF Arthroscopic Probe, when used in conjunction with the Dyonics Control RF Generator Adaptor is intended for resection, botation, or excision of soft tissue; hemostasis of blood vessels and coagulation of soft tissue in patients requiring enthroscopic surgery of the knee, shoulder, antide, efbow, wrist, and hip.

CONTRAINDICATIONS

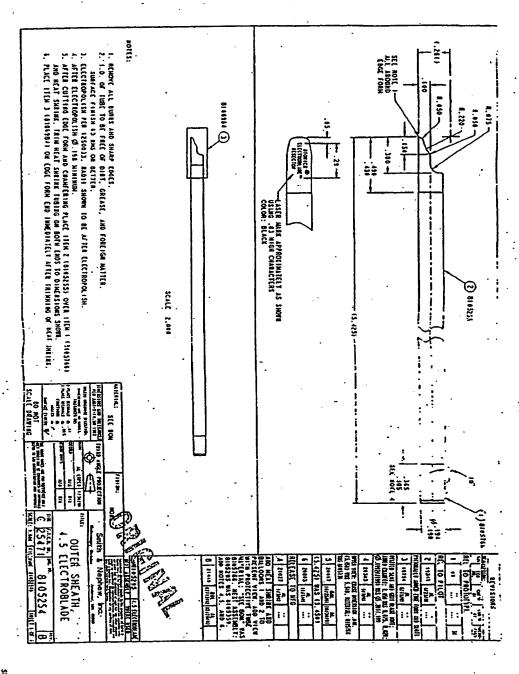
Use of the Dyonics Series 7000 RF Arthroscopic Probe is contraindicated in any non-arthroscopic surgical procedure and in procedures where saline, Ringer's loctate, or other conductive solution is not used as an irrigant. The probe is not appropriate for patients for whom an arthroscopic procedure is contraindicated for any reason. Use of the Dyonics Series 7000 RF Arthroscopic Probe is contraindicated for patients with heart pacemeters or other electronic device implants.

WARNINGS

- . Use only with the Yalleylab Force FXTM or Ferce FXTM-C Generator and the Smith & Nephew RF Generator Adapter.
- The power settings provided in this document are for reference purposes. Use the lowest power setting and minimum tissue contact time necessary to achieve the appropriate surgical effect to avoid unintended tissue injury.
- . Do not teach the ceramic tip or electrode when power is being applied.
- Avoid touching the curamic tip or electrode with your fingers or instruments.
- . De not insert or withdraw the probe while power is being applied.
- Inadvertant activation or movement of the electrode outside the field of vicion may result in patient injury.
- . Avoid ennoccessiry or prolonged activation between tissue applications as unintended injury may result.
- Avoid bubble accumulation in the joint space during use. The accumulation of bubbles around the working tip of the probe util
 diminish performance and may produce everheating sufficient to demage adjacent structures.
- . Contents sterile. Do no use it package has been opened or damaged.
- De not purse any accessories labeled as SINGLE USE.
- . Using arthroscopic guidance, ensure that the probe tip is completely surrounded by conductive integrat solution during use.

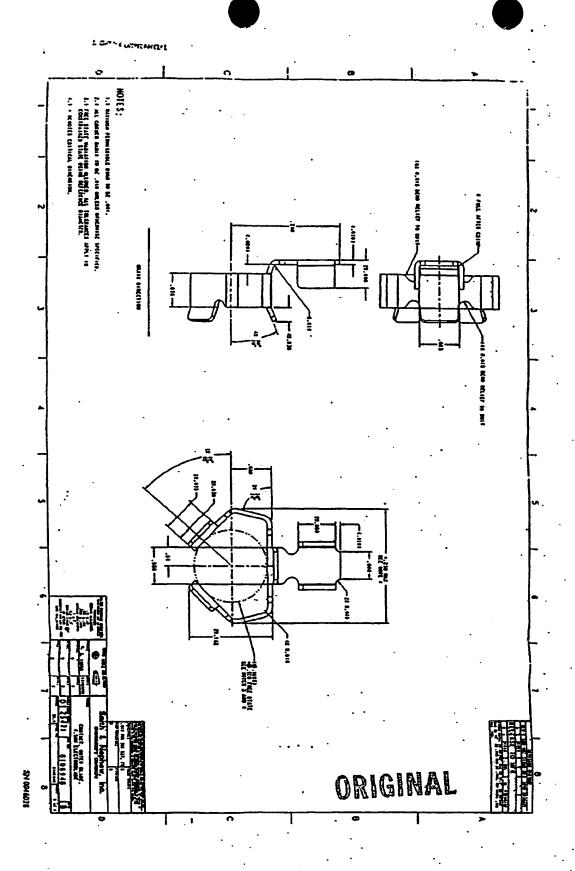


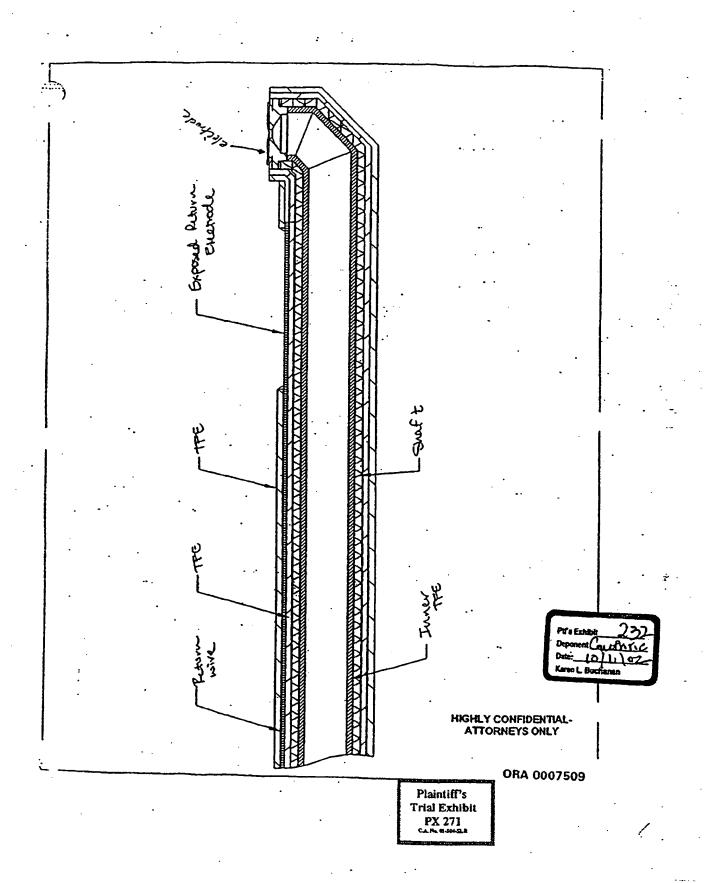




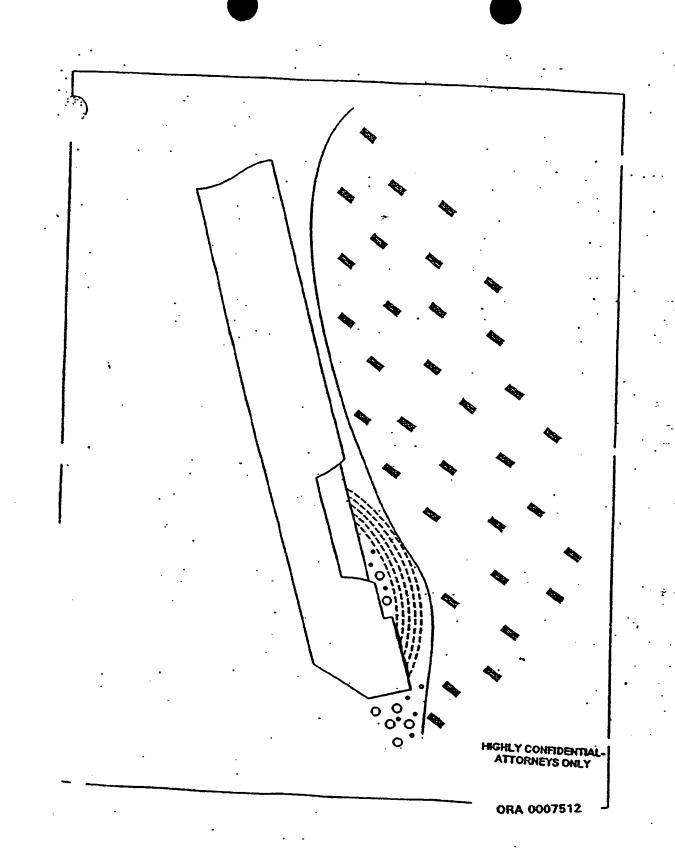
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A 22775



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MP100222 Rev.02A

TITLE: CABLE TO SHAFT WELDING FOR INTEGRATED CABLE

Revision History

Rev.	DCO/LAS#	Effective Date	Description of Change .	Initiator
01	D010496	08/03/01	New Release	Andy Suresh
. 62	D010519	08/21/ 0 1 - -	 Added MSP200731 to section 5.7, and section 9.1.4 for changing the electrode tip. Revised sections 9.1.3 cleaning the electrode up, 9.1.6.1 check electrode force with no weld, and 9.2.11 holding the cable up, and 9.3.1 for damaged power wire. 	Tan Huynh

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Plaintiff's Trial Exhibit PX 310 Page 1 of 7

MP160222 Rev.02A

TITLE: CABLE TO SHAFT WELDING FOR INTEGRATED CABLE.

OBJECTIVE

This MPI provides instructions for welding the power wire to the bipolar probe shaft and 1.1 soldering the return wire for TAC, Chisel. Ablation and Ablation Suction shafts.

REFERENCE

- 2.1 SOP00012 Line Clearance
- AFFECTED DEPARTMENT.
 - 3.1 Production
- DEFINITIONS 4.0
 - 4.1 N/A-
- 5.0 **EQUIPMENT**
 - 5.1 Resistance Welder OMC00031
 - 5.2 Power Wire Welding fixture MSP200408
 - 5.3 Safety glasses
 - 5.4 Scale (Ruler), Graduated in 0.01"
 - 5.5 Eraser stripper OMC00104
 - 5.6 Dental mirror
 - 5.7 MSP200731 Electrode Tip Cleaning Tool
 - 5.8 Microscope
 - Soldering iron
 - Continuity meter
- 6.0 **MATERIALS**
 - Prosat wipes P/N 300073 6.1
 - 6.2 JPA.
- LINE CLEARANCE AND CLEANING
 - 7.1 Clear area of parts not related to this assembly, refer to SOP00012, Line Clearance Procedure.

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MP100222 Rev.02A

TITLE: CABLE TO SHAFT WELDING FOR INTEGRATED CABLE

7.2 Clean work area by wiping with Prosat wipes.

8.0 SAFETY

- 8.1 If unfamiliar with the use of the resistance welder, contact manufacturing supervisor prior to use.
- 8.2 Wear safety glasses when using resistance welder, if microscope is not used.

9.0 PROCEDURE

- 9.1 Set-up
 - 9.1.1 Set up welding machine.
 - 9.1.2 Install Cable Guide MSP200397 on fixture to weld non-suction probes, or Cable guide . MSP200668 to weld Suction Probes.
 - 9.1.3. Clean the top and bottom electrode prior to lot start and after welding every 30 units. Electrodes should be cleaned using the electrodes cleaning tool MSP200731. Use mirror to inspect any visible signs of damage on the top electrode. Refer to figure #6.
 - 9.1.4 Replace the top electrode when the wire or shaft sticks to the electrode, or excessive sparkling occurs.
 - 9.1.5 Turn on the resistance welder.
 - 9.1.6 At the beginning of the lot do the following:
 - 9.1.6.1 Check electrode force to 8 lbs with resistance welder on no weld.
 - 9.1.6.2 Select the preset schedule (Schedule 1: 1" Pulse = 22.5 %, 2" Pulse = 45 %).

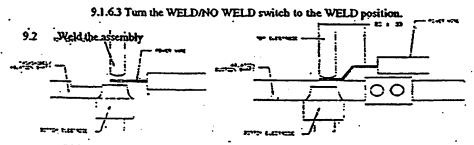


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MP100222 Rev.02A

TITLE: CABLE TO SHAFT WELDING FOR INTEGRATED CABLE

- 9.1.19.2.1 IPC: Before welding, verify orientation of the front and rear grommet as shown in Figure 2 and 3.
- 9.2.2 IPC: Inspect the integrity of the tinned wires before welding. ITher should be tinned all around the wire. There should be no loose wires and the tinned portion should be within 0.10" ±0.02". If the tinned wire does not meet this criteria, send them to the supporter area to be reworked.
- 9.2.3 Position the shaft to the groove on the shaft supporting block of the welding fixture as shown in Figure 1 with the notch facing up for TAC, Chisel and Ablation shafts, and the tip facing away from the operator for the Ablation Suction and bipolar shafts. For non-suction shafts, make sure that the proximal end of the notch on the shaft is aligned with the edge of the top electrode. Refer to figure 1.
- 9.2.4 Confirm the shaft is resting on the bottom electrode.
- 9.2.5 Align the power wire to the cable guide block of the fixture
- 9.2.6 For the TAC, Chisel and Ablation shafts: The distal tip of the power wire should be located at the proximal end of the notch.
- 9.2.7 For the Ablation Suction shaft: The distal tip of the power wire should be located within 0.2" from the distal end of the crimp ring. Refer to figure 5 for the orientation of the shaft tip for suction shaft.
- 9.2.1 Position the power wire along the groove of the cable guide block of the fixture such that the power wire is resting on top center of the shaft, the power wire is parallel, and the tip of the power wire is flush with the left edge of the top electrode. Refer to figure 1. Take care that the wire is not touching the Crimp Ring on suction probes.
- .9.2.9 Lightly step on the foot pedal so that the top electrode comes down and contacts the power wire.
- 9.2.10 Consirm the left edge of the top electrode tip aligns with the tip of the power wire. Refer to Figure. 1 for power wire and shaft position. Also confirm that the tip of the power wire is centered to the top electrode and on top of the shaft. Refer to figure 6.
- 9.2.11 IPC: During welding, the bottom electrode and the power wire should not touch the crimp ring by holding the cable up from the shaft.
- 9.2.12 If the position of the shaft and power wire meet the above requirements, apply additional pressure to foot pedal to weld the power wire to the shaft.

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MP100222 Rev.02A

TITLE: CABLE TO SHAFT WELDING FOR INTEGRATED CABLE

9.2.13 If In-process Kanban Cards are present at the downstream end of the operation, then use a maximum In-process Kanban Quantity of 5.

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MPI00222 Rev.02A

TITLE: CABLE TO SHAFT WELDING FOR INTEGRATED CABLE

- 9.3 IPC: Inspect weld spot with a microscope.
 - 9.3.1 Weld spot should show no signs of excessive melting or broken spot on the power wire and shaft.
 - 9.3.2 Wire should not be welded to Crimp Ring (suction)
 - 9.3.3 Wire should not protrude into notch (non-suction).
- 9.4 Solder the return wire 9.41A Cut Hack integrated existe wire to . 100"- 120"
 - 9.4.) Use a razor blade to scrape clean .125" of the proximal end of the ribbon wire. Solder the black integrated cable wire to the ribbon wire at icast .100" distal from the trimmed end of the bottom layer of shrink tubling. The solder joint can not short or contact the shaft.

 When the conductive weathers with up to the contact the shaft.
 - 9.4.2 Clean flux using IPA.
- 9.49.5 IPC: Gently tug on the power wires to make sure it is they are securely welded-attached in place.
- 2.6 IPC: Check for shorts between the black and white integrated cable wires using a continuity meter or buzzer.
- 9.59.7 Assembly of the PVC tubing on suction shaft.
 7.7.1 Car a .500 1 250 exec of population thanks. Added to the form the granules.
 9.7.13 Heat the distal end of the PVC tubing using a hot box at 350° + 5° F for 10 seconds.
 - 9.5.12.7.21 Slide the PVC tubing on to the proximal end of the suction chaft and make sure that there is a range of .08" to 0.10" gap between the crimp ring and the end of the PVC tubing. Refer to Figure 4 inner TFE to the end of the shaft.
- 10.0 ACCEPTANCE CRITERIA
 - 10.1 Power wire is securely welded to shaft.
 - 10.2 Weld spot has no signs of excessive melting or broken spots on the power wire.
 - 10.3 The black and white integrated cable wires are not shorted to each other.

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MP100222 Rev.02A

TITLE: CABLE TO SHAFT WELDING FOR INTEGRATED CABLE

.11.0 DIAGRAM

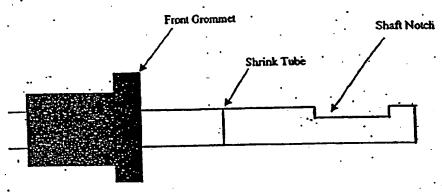


Figure 2: Orientation of Front Grommet on the shaft

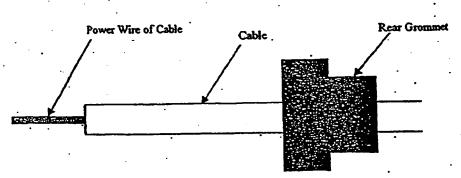


Figure 3: Orientation of Rear Grommet on the Cable

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TITLE: CABLE TO SHAFT WELDING FOR INTEGRATED CABLE

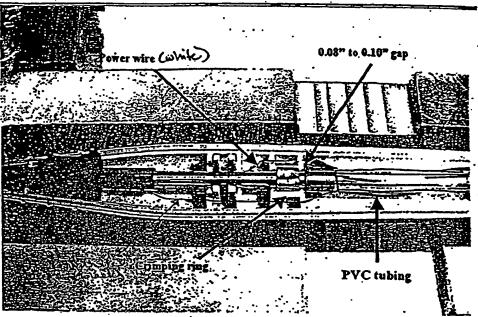


Figure 4: Location of crimp ring on suction and routing of power wire.

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TITLE: CABLE TO SHAFT WELDING FOR INTEGRATED CABLE

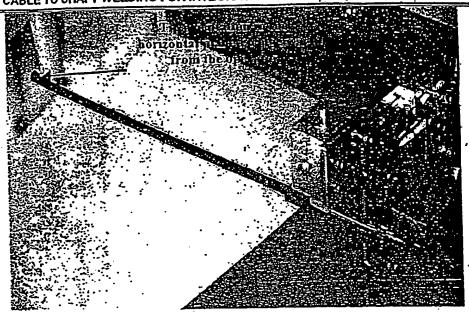


Figure 5: Showing the orientation of the suction tip while resistance welding

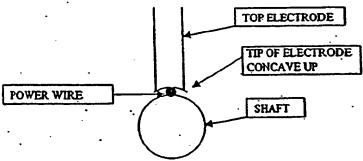


Figure 6: Power wire and Shaft is centered with the Top Electrode

12.0 DOCUMENTATION

12.1 Record manufacturing information, date and sign on the Device History Records (DHR).

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.MP100220/. . (Temp.)

TITLE: CABLE AND SHAFT PREPARATION FOR INTEGRATED CABLE PROBE

Revision History

Rev.	DCO/LAS#	Effective Date	Description of Change	Initiater
01	.D010496	08/03/01	New Release	Nicole Perez
Temp.	D010524	08/17/01	Revise section 9.1.1	Andy Suresh

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MP100220 ... Rev.01 (Temp.)

TITLE: CABLE AND SHAFT PREPARATION FOR INTEGRATED CABLE PROBE

1.0 OBJECTIVE

1.1 This MPI provides instructions for Preparation of cable wire for TAC, Chisel, Ablation, and Ablation Suction shafts.

2.0 REFERENCE

2.1 SOP00012 Line Clearance

3.0 AFFECTED DEPARTMENT

3.1 Production

4.0 DEFINITIONS

4.1 NA

5.0 EQUIPMENT

- 5.1 Safety-glasses
- 5.2 Front Grommet Assembly Fixture (MSP200605).
- 5.3 Rear Grommet Assembly Fixture
- 5.4 Wire Strippers, 24 AWG
- 5.5 Scale (Ruler), Graduated in 0.01"
- 5.6 Eraser stripper OMC00104
- 5.7 Solder Pot

6.0 MATERIALS

- 6.1 Proset wipes P/N 300073
- 6.2 Lint Free wipes
- 6.3 70/30 IPA
- 6.4 Finger cots or Gloves

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7.0 · LINE CLEARANCE AND CLEANING

- 7.1 Clear area of parts not related to this assembly, refer to SOP00012, Line Clearance Procedure.
- 7.2 Clean work area by wiping with Prosat wipes.

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MP100220 Rev.01 (Temp.)

TITLE: CABLE AND SHAFT PREPARATION FOR INTEGRATED CABLE PROBE

8.0. SAFETY

8.1 Wear safety glasses when using Solder Pot.

9.0 PROCEDURE

- 9.1 Prepare Cables in supporter area.
 - 9.1.1 Power wires preparation.
 9.1.1.14 For Bipolar Probes 1800 ptus aver jacked 2" ± 0.2".
 - 9.1.1.1 For Suction Probes only: Measure the stripped section of the grey jacket.

 The stripped section should measure 1" +/- 0.2". If not, strip the grey jacket 1"
 +/- 0.2".
 - 9.1.1.2 Twist or pull one end of cable to remove the outer grey insulation of the wires.
 - 9.1.1.3 Strip power wire to expose the conductors to 0.55" to 0.65" and then twist the small wires together. If needed use finger cots or gloves to twist the wires.
 - 9.1.1.4 Dip the twisted wire into the 70/30 IPA and dry with lint free wipes.
 - 9:1.1.5 Dip the endsof the stripped section into a solder pot to tin 0.20" to 0.30" of the wire tip(14 1/21/61
 - 9.1.1.6 Trim the exposed conductors such that the timed section is 0.10" \pm 0.02".
 - 9.1.1.7 IPC: Inspect if 0.10"± 0.02 of the tip of the power wireje fully tinned.
 - 9.1.1.3 For cables with IC Wires, suip approximately 0.3°1 0.1 from each end of the IC Wires.
- 9.2 For shafts that are coated by supplier, inspect the coated shaft for the following:
 - 9.2.1 Visually inspect the insulation under 1X magnification with probe held at 18" away.
 - 9.2.1.1 Reject any pinholes, cuts or deep scratches exposing metal.
 - 9.2.1.2 Reject if scratches, embedded particles, discoloration spots are located within distal 1" of probe.
 - 9.2.1.3 For scratches, embedded particles, discoloration spots located beyond distal 1" of probe, reject if:
 - 9.2.1.3.1 More than four are found in any combination.
 - 9.2.1.3.2 Any scratch longer than 0.08".

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MP100220 Rev.01 (Temp.)

TITLE: CABLE AND SHAFT PREPARATION FOR INTEGRATED CABLE PROBE

9.2.1.3.3 Any embedded particles or discoloration spot larger than 0.05" in, diameter.

- . 9.2.2 Put the protective sleeve over the coated shaft.
- 9.3 Assemble cable and PVC tubing on the rear grommet from supporter area.
 - 9.3.1 For non-suction probes, slide the rear grommet over the cable to about 3.5" from the tip of the power wire using rear grommet fixture. Refer to Figure 2 for orientation of the rear grommet on the cable.
 - 9.3.2 Assemble the front grommet on to the shaft using the front grommet assembly fixture. Refer to Figure 1 for orientation of the front grommet on the shaft.
 - 9.3.3 For suction probest slide the rear grommet over the cable and the PVC tubing to about 3.5" from the tip of the power wire. Make sure that the PVC tube is inserted into the larger hole in the rear grommet. Refer to Figure 2 for orientation of the rear grommet on the cable.
 - 9.3.4 Assemble the front grommet onto the shaft using the front grommet assembly fixture MSP200605 refer to figure 1 for orientation of front grommet on the shaft.
 - 9.3.5 Note: To rework shafts with excess power wire, use a file to take off the excess wire, by filing down the excess wire until the shaft is free of excess wire.

10.0 ACCEPTANCE CRITERIA

- 10.1 Visually inspect the stripped power wire if tinning is within spec of 0.10"± 0.02.
- 10.2 Visually inspect if the tinned section of the power is not frayed.

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MP100220 'Rev.01 (Temp.)

TITLE: CABLE AND SHAFT PREPARATION FOR INTEGRATED CABLE PROBE

11.0 DIAGRAM

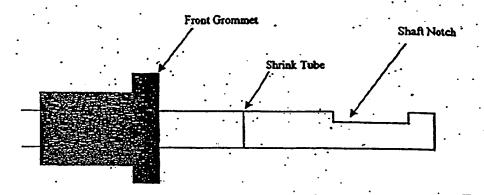


Figure 1: Orientation of Front Grommet on the shaft

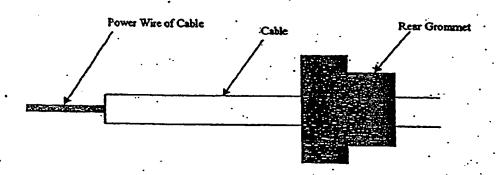


Figure 2: Orientation of Rear Grommet on the Cable

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MP100220 Rev.01 (Temp.)

TITLE: CABLE AND SHAFT PREPARATION FOR INTEGRATED CABLE PROBE

12.0 DOCUMENTATION

12.1 Record manufacturing information, date and sign on the Device History Records (DHR).

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Rob Griffi

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Plaintiff's Trial Exhibit PX 324

A 22803

Managing Surgeon Expectations

- Saphyre Suction Probes
- Saphyre suction design will clear bubbles and debris quickly, and efficiently
- During use, keep the electrode level with the target tissue for optimal evacuation of bubbles
- Start your surgeon at the pre-set of 120 watts
- Suggest setting the suction control valve to wide-open

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Managing Surgeon Expectations

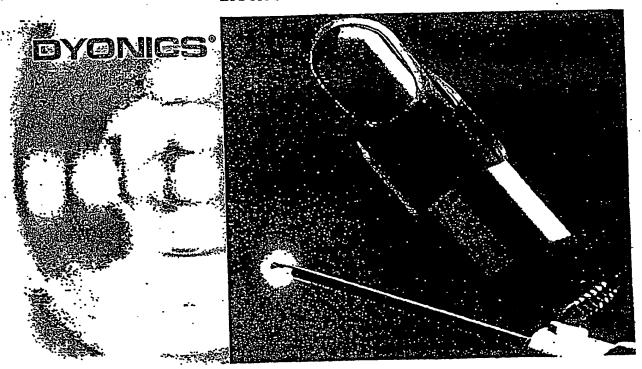
Tight seal between probe and tissue causes steam bubbles to form under electrode, which allows an arc to be created and ablation to occur.

ArthroCare calls this plasma formation

ORA 06509

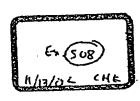
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Dyonics^o Series 9000 ElectroBlade[®] Resector



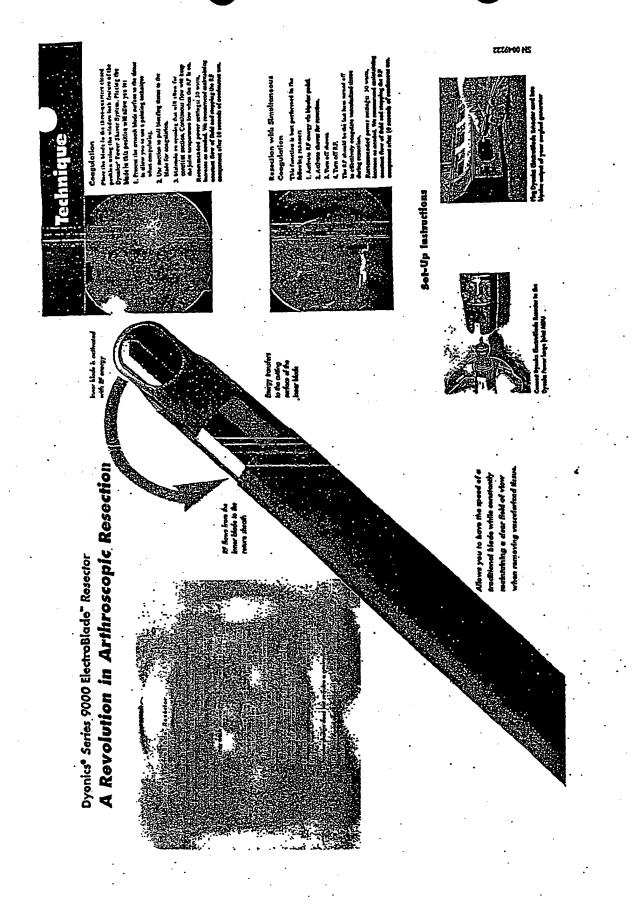
The world's first arthroscopic product to mechanically resect soft tissue and simultaneously provide coagulation!

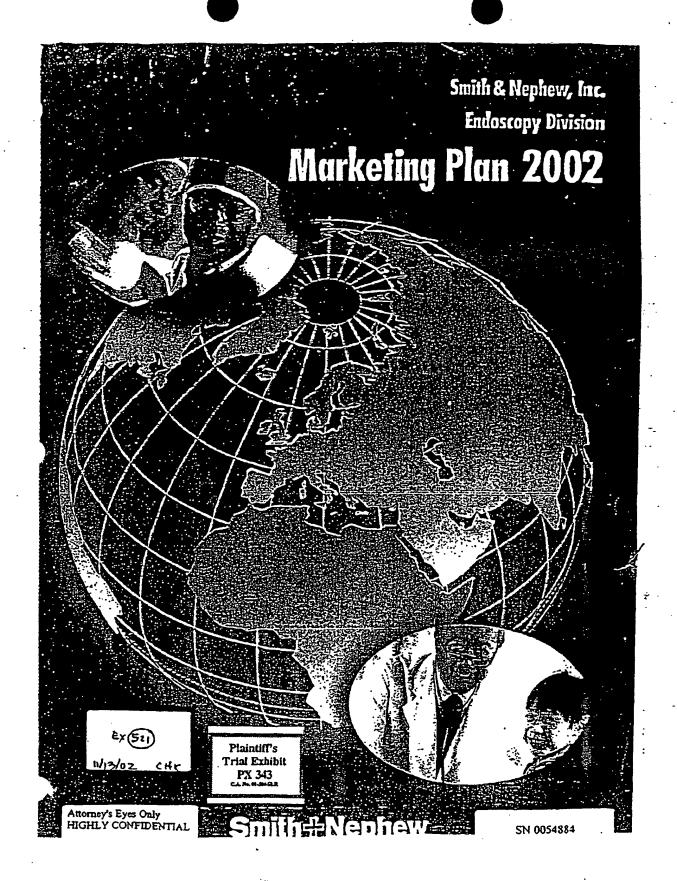
Smith Nephew



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Company	i di Socijali (1980) (1984)	Collination of the second	Se Organization Services	Winner Street West Commence
Orates	Most extensive experience with thermal shrinkage Continually improve existing product (i.e., Vulcan system, new suction probes) Only device with temperature control	Perceptions reality of	Establish temperature- control platform for large potential segments such as articular cartilage Differentiate as clinical leader w/published	Poot long-term clinical results wishrinkage Competitors produce equal or better shrinkage results Competitors leverage-bundle with other equipment Company's spine segment will stohon off funds for arthroscopy
Mitek	Solid ablation product, recent introduction of thermal version. Leverage with shoulder products. Respected, physician-focused salesforce. Recent upgrades include temperature controlled generator. Strongest European presence due to Ethicon.	OEM from Gyrus Current focus on shoulder segment only Has not established credibility for thermal shrinkage. Design does not allow for suction; use "sheath" with limited success	Innovasive will expand full line opportunity Establish clinical efficacy/superiority of VAPR II for thermal strinkage and ablation Develop next-generation devices	Share same niche position as Arthrex/ArthoCare, confusing to customers OEM product < margins, profitability will decline wraggressive bundling
Anthrocare	First to market w/bipolar ablation product Considered "gold standard" for product performance Leverage with Arthrex product in US Strong patent position	Lack Mitek's financial resources Niche player in overall arthroscopy market	Leverage wands with Arthrex products Establish elinical efficacy/superiority of thermal products	Declining profit margins with OEM/free box; declining ASP for leverage Increased competitors will speed market maturation Inability to gain broad acceptance for articular cartilage will snamp growth
Stryker	Strong recognition in visualization market	#3 position in powered resection market	Lever RF for a complete system sale	Poor customer acceptance if function appears inferior to Arthrocare or Misek
invalec	Broad product line Perceived as low-cost supplier	Monopolar device minimally differenced from "Bovie pencil" Low customer recognition acceptance of device	Establish clinical equivalence to established competitors and low-cost platform Broad bundling capability	Failure to create a distinction from Bovie Nonexistent promotional efforts

Figure 7-60 RF Competitor SWOT Analysis

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Smith & Nephew Endoscopy

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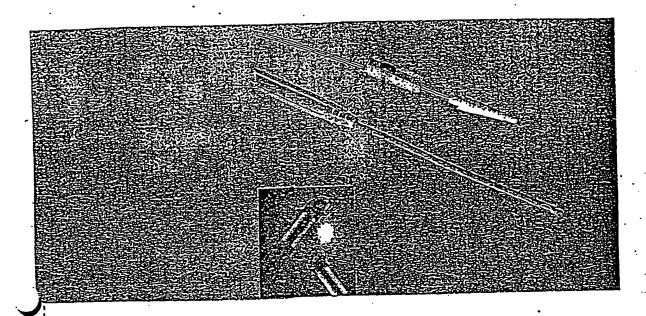
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Saphyre Bipolar Ablation Probes Smith & Nephew ElectroThermal Arthroscopy System (EAS")



Sales Guide

Prepared by the Marketing and Sales Training Departments

Plaintiff's Trial Exhibit PX 390

Software Upgrade Guide on Page 13

SmithNephew



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ORA 0052390

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Introduction

The acquisition of ORATEC Interventions by Smith & Nephew Endoscopy Division provides a unique opportunity to combine the strengths of Smith & Nephew in arthroscopic visualization and resection with the technology leadership position ORATEC had established in radiotrequency (RF) systems and applications. The ORATEC product line has been known as the "monopolar" RF technology in the marketplace, and there certainly are numerous advantages to the use of monopolar RF energy delivery in certain applications. As we turther the integration of the former ORATEC products into the Smith & Nephew Electrothermal Arthroscopy System (EAS), we want to act quickly to extend the product offering to include bipolar ablation.

This Sales Guide will initiate the launch of the new Saphyre™ Bipofar Ablation Probe product line. The addition of Saphyre Bipofar Ablation Probes rounds out our electrothermal arthroscopy product line. The Smith & Nephew EAS is the only arthroscopy system available anywhere that can operate in both monopolar and bipofar energy delivery modes. Our customers will now have the convenience and freedom of choice to move between these two tools freely, using the Vulcan® Generator. You can look forward to some true competitive advantages from these customer benefits.

In the Sales Guide, you'll learn about Saphyre Bipotar Ablation Probe Features and Benefits, how these products compare with competitors, and our strategies for approaching customers successfully. A key element to keep in mind is that we will not obsolete the monopolar Ablation Probe product line. Smith & Nephew has many customers that are completely satisfied with the performance of the monopolar ablation products. It is undesirable for us and undesired by the customers to convert these accounts to bipotar ablation. You will be given some very specific direction regarding account targeting and the rollout of Saphyre Bipolar Ablation products. Let's use the launch of Saphyre Bipolar Ablation Probes to grow the business!

Please study the contents of the Sales Guide thoroughly. This material complements the Web training material. We expect you to know this material and to return and pass the enclosed Assessment before your sales samples and literature will be sent to you. Questions concerning any of this information or any issue relating to the launch of Saphyre Bipotar Ablation Probes should be addressed to the Marketing Department.

Thank you and Good Selling!!

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4	Product Objectives
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Product Description

Saphyre bipolar ablation probes bring bipolar modality to life for the Smith & Nephew Vulcan generator. Simply put, the probes are disposable, bipolar electrosurgical probes for cutting, ablating and coagulating soft tissue. But there is also so much more!

Saphyre bipolar ablation probes are designed to be competitive with existing bipolar and monopolar products currently on the market. They are intended to build RF sales where monopolar Smith & Nephew products have been unable to gain ground against competitive bipolar ablation sales.

To this end, Saphyre probes offer several features to stand out against the competition.

- Jewel cut, notched electrode for fantastic ablation performance
- Protected back-side of the distal shaft to minimize collateral tissue damage, called the CoolBack™ insulated shaft
- Integrated Cable
- · Excellent coagulation ability
- · Suction and non-suction available
- · High profile tips available
- Part of the Vulcan family, with auto-probe recognition and software centrols

Saphyre probes stand out with a gray color-scheme to differentiate it from other Smith & Nephew probe lines. The double-walled shaft insulation and integrated cable connector are both gray, as is the box label color scheme.

The Saphyre line is available in the following models:

Saphyre 90°, 3mm

Saphyre 60°, 3mm

Saphyre 90°, 3mm High Profile

Saphyre 90°, 3mm with Suction

Saphyre 60°, 3mm with Suction

Saphyre 90°, 3mm High Profile with Suction

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770140 Rev. 01

3

Saphyre™ Product Objectives

Market Objectives

Saphyre probes put the Smith & Nephew Vulcan ElectroThermal Arthroscopy System ahead of all competitors. Our objectives are to:

- Successfully launch Saphyre probes with target sales of \$3.4 million in 2002
- Demonstrate Smith & Nephew's ElectroThermal Arthroscopy System superiority using Saphyre probes
- Capture an additional 8% market share in ablation, to a total 18% share
- Abstain from cannibalization of current monopolar ablation business

Customer Targets

Prioritizing your customers into specific targets will give you the best chance of capturing significant bipolar ablation business while minimizing the impact on your current monopolar ablation shipments. Here are the customer largets we want you to go after.

- Platinum Smith & Nephew Endoscopy Dyonics™ Shaver accounts with competitive RF products.
 - You can offer these customers the terrific advantage of having a single supplier for all their arthroscopic resection instruments. Streamlined ordering and pricing packages are available for them.
- Accounts that exclusively use competitive (bipolar) ablation, but have the Vulcan generator in place for temperature control procedures.

These customers should give you an instant "in" because they already use Vulcan generator for temperature control with TAC probes. Your objective is to get them to evaluate and convert to Saphyre bipolar ablation probes. Offer them the advantage of consolidating to one RF arthroscopy system.

NOTE:

We are specifically not targeting accounts where Smith & Nephew monopolar ablation probes are used exclusively or extensively. We already have the business there! Let's use the launch of the Saphyre probes to obtain new business. Do not cannibalize our existing monopolar probe volume. These customers are happy with their monopolar ablation products, and should not be visited with Saphyre probes unless independently requested by the surgeon.

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Product Summary

- Smith & Nephew ElectroThermal Arthroscopy System
 - The most complete system for Electrothermal Arthroscopic surgery available today!
 - The only system that combines rapid-response tissue temperature control with automatic probe recognition.
 - The world leader in thermal modification of soft tissues in arthroscopic procedures.
 - The only system offering probes with Integrated disposable cables. No need to clean and resterilize reusable cables!

◆ Saphyre Probe

- The only probe available with CoolBack™, virtually eliminating risk of tissue damage from a hot return electrode that may be out of the field of view.
- In combination with the probe-recognition of the Vulcan generator and integrated cable, the most convenient choice in bipolar ablation
- Part of the Smith & Nephew EAS family of probes, the most complete Electrothermal Arthroscopy System on the market.
- The newest, easiest to use bipolar ablation probe on the market loday!

Monopolar Ablation

There is no plan to obsolete or reduce emphasis on this portion of the product line. In accounts satisfied with monopolar ablation, there is no need to launch bipolar. Here is a synopsis of the positioning of monopolar ablation:

- Exceptional ablation performance within the Smith & Nephew EAS family.
- The convenience of integrated cable with the confidence of monopolar technology.
- Lower cost for the customer than bipolar ablation probes from competitors or from Smith & Nephew (see price fist for details).
- Monopolar is established and accepted technology for both temperature control and ablation applications.

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5

Smith & Nephew's Strengths and Weaknesses

To expand Smith & Nephew's strong leadership position in the arthroscopy market an all-in-one RF system has been added to Smith & Nephew's broad repertoire of products for resection, repair, visualization, and access. The new all-in-one ElectroThermal Arthroscopy System has key strengths to solidify Smith & Nephew's position as market leader of the arthroscopic resection market while overcoming the obstacle of being known as the "monopolar system":

Charathe	Weaknesses ·
Strengths Broadens comprehensive line of quality products for anthroscopic resection, repair, visualization, at access by creating a single sound supplier	nd
 Large global sales force with a broad procedure knowledge and strong customer relationships 	
 Already established market shart the anthroscopy market with \$27 million in sales for 2001 	re in
 All-in-one system allows the customer to resect, contract, an coagulate with monopolar and bipolar capabilites-no one else i the market can provide this 	
 Strengthens leadership position the arthroscopic market and specifically arthroscopic resecti 	

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Smlth & Nephew Market Strategies

The Smith & Nephew ElectroThermal Arthroscopy System (EAS) is the most complete RF system on the market today. With the launch of the Saphyre bipolar ablation line of probes, Smith & Nephew has the ability to take a commanding lead in the marketplace. Smith & Nephew already is the leader in thermal modification of soft tissues with the Vulcan generator, and the Saphyre line has the potential to propel the entire Smith & Nephew product line into a market leadership position.

The following strategies are key to the success of the launch of the product line.

Strategy #1:

Differentiate the Smith & Nephew EAS from all

competitors.

Tactic:

Be sure to investigate your customer's situation and usage of RF before pulling out the Saphyre probe. When you understand their needs, clearly position and explain its

benefits as part of the full Smith & Nephew system.

Tactic:

Develop surgeon champions in your territory. Explore the interest from your most credible surgeons to support your sales efforts in other accounts. Often surgeons that are satisfied with our products will help to break the ice with

other decision makers

Strategy #2:

Leverage Smith & Nephew as a Sole Source

Supplier

Tactic

Target existing accounts that are current Smith & Nephew resection customers AND are Vulcan accounts not using

monopolar ablation.

Tactic: ·

Emphasize full offering of RF arthroscopy products: Temperature control and ablation; wrist, ankle and hip applications; monopolar and bipolar modalities. This approach leverages sales of all probe types when the Saphyre products or the Vulcan Generator is introduced.

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Tactic:

Leverage leadership in arthroscopy and RF technology at key events and training opportunities.

AANA, ESCA, AOSSM conferences Orthopedic Learning Center courses

Tactic:

Maximize incremental business using Saphyre probes.

NOTE:

We are specifically not targeting accounts where Smith & Nephew EAS monopolar ablation probes are used exclusively or extensively. We already have the business there! Let's use the launch of the Saphyre line to obtain new business. Do not cannibalize our existing monopolar probe volume. These customers are happy with their monopolar ablation products, and should be visited with Saphyre probes only il necessary.

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Saphyre Line Features and Benefits

The all-in-one Smith & Nephew ElectroThermal Arthroscopy System allows the surgeon to resect, contract, and coagulate using innovative monopolar and bipolar technology. Having all of these options available in one box simplifies purchasing and set-up while reducing inventory needs for the customer. Features and benefits covers both the Saphyre line and how it integrates with the Vulcan generator.

Features .	Benefits
Bipolar ablation design	Teams aggressive ablation with enhanced, global coagulation performance
All-In-One System	Provides the customer with one system for tissue resection and contraction with a choice of monopolar or bipolar modalities
Innovative electrode design with notched face and energy directing flutes	Enhances ablation performance to maximize tissue effect, especially on frond-like tissue
CoolBack design with insulation on entire shaft except for exposed antenor return electrode	Focuses ablation effect toward active electrode where it is needed, while the insulation on the posterior portion of the shaft minimizes inadvertent damage to collateral tissue
Integrated Cable	Ensures easy connection with Vulcan generator. Eliminates handling of reusable cables
Color coded shaft insulation and connectors for each family of probes	Allows for easy recognition of and differentiation between each probe type
Field-Upgradable System	Allows for updating Vulcan generators in the field so the customer always has the latest technology available, with no downtime.
Suction with adjustable flow control	Improves visualization by reducing "snowy" arthroscopic field, removing small tissue particles and bubbles HIGHLY CONFIDENTIAL

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Ablation Market Segments and Technical Review

The RF arthroscopy market is founded on cutting and ablation applications, making up about 90% of all RF cases. Temperature control or tissue contraction markets comprise only about 10% of the RF procedures performed in today's market. The growth potential for both areas is enormous. This section reviews technical and clinical use of the Saphyre probes.

Technical Review

The Saphyre probe is an ablation probe intended to resect soft tissue and perform hemostasis (coagulate blood vessels). Like all ablation probes, Saphyre probes are intended to rapidly remove soft tissue to achieve a clinical result, such as reducing inflammatory agents, creating room for visualization in the joint space or gaining access to anatomical regions undemeath the soft tissue.

Cutting and ablation is generally performed with high <u>power levels</u>, from 90 to 200 watts. Coagulation can be achieved with 30 to 60 watts (higher temperatures tend to ablate blood vessels not coagulate them to stop bleeding). The Vulcan software defaults to 120 watts for Cut, and 50 watts for Coag when a Saphyre probe is connected. Settings for both Cut and Coag can be manually adjusted between 5 and 160 watts for the Saphyre probes.

To use a Saphyre probe, the surgeon does not need to maintain full electrode contact on the tissue. This is different than the monopolar Ablator technique, where full electrode contact IS necessary to achieve an arc. Saphyre probes may arc when activated at high power (120 watts or greater) in the conductive irrigant. This is very helpful for removing frond-like or wispy tissue.

Additionally, <u>bleeders</u> can be addressed by moving the Saphyre probe in the region of the open vessel, versus actually making direct contact with the bleeder as needed with the monopolar Ablator. This is because a bipolar probe creates a pocket of heat around the active electrode. It may only be necessary to get close to the bleeder rather than touch it directly.

The return electrode on the distal shaft does heat up when energy is activated. It will not get as hot as the active electrode (tip), but it may be hot enough to thermally damage tissue. This effect is common to all bipolar RF arthroscopy probes. It is the reason that Saphyre probe was designed with an insulated back-side on the distal shaft. Unwanted tissue damage can occur when the return electrode touches tissue that is not part of the treatment area. Protecting the patient and giving the doctor the safest features is one of the great advantages of the Saphyre probe design.

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A <u>conductive irrigation solution</u>, such as Lactated Ringers or sterile saline, is required for arthroscopic electrosurgical procedures. Sterile water should not be used. In addition to creating an electrolytic imbalance in the joint tissue, sterile water will inhibit the arcing and heating that is required to electrosurgically remove tissue.

A grounding pad (return electrode pad) is not required for use with the Saphyre probe. However, if the surgeon will be using another Vulcan probe, such as a TAC or Ligament Chisel, a grounding pad will need to be placed on the patient during the procedural set up. [Refer to Good Practices for Ground Pad Placement document available from Customer Service.] If a grounding pad connects the patient to the Vulcan and a Saphyre probe is used, there is no conflict. Vulcan recognizes that the Saphyre probe is a bipolar probe and the software disables the grounding pad and NEM circuits. In other words, in bipolar mode the Vulcan ignores an attached ground pad and the NEM light will be blank.

Saphyre probes are <u>not malleable</u>. One reason is that the return electrode or its power wire may be damaged if bent in the distal portion. This could render the probe non-functional in the bipolar mode. Also, there is a risk of occluding or crimping the suction tube inside the shaft of a suction probe. If this were to happen, visibility could be greatly reduced and fluid trapped in the distal portion of the probe could become heated.

Applications

Regulatory advisement.

Physicians use RF ablation in a variety of procedures. Saphyre probes cannot be marketed for use in any specific application or specific joint at this time because of the level of regulatory clearance currently on file. Monopolar Ablators can be marketed for specific applications and joints.

The review of applications that follows is typical of the RF ablation market in general. Hemostasis may be performed in all of these and many other arthroscopic procedures.

Shoulder applications

Common ablation uses in the shoulder include:

Subacromial decompression

Surgeons ablate the soft tissue on a bone spur under the acromion. The spur is then buried down to relieve compressive pain. This is the most common arthroscopic procedure using RF ablation.

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- Excision of scar tissue
- · Debridement of the rotator cuff
- Capsular release
 Cutting of the capsular tissue to open up the joint

Knee applications

Common ablation uses in the knee include:

- Excision of torn anterior cruciate ligament (ACL) or posterior cruciate ligament (PCL)
- Notchplasty

 Debridement of the ACL or PCL notch after figament removal.

 Cleans out the figament stump in preparation for figament repair
- Synovectomy Removal of inflamed synovial lining
- Partial meniscectomy
 Sculpting or smoothing of torn meniscal cartilage to preserve remaining healthy tissue. RF abilition will generally not remove or cut away significant sections of meniscus
- Ablation is NOT recommended for use on articular or hyaline cartilage, such as in femoral or patellar chondroplasty. Preservation of living chondrocytes in articular cartilage is critically important. Ablation may cause extensive damage to this tissue. Temperature-controlled or mechanical tissue effects are much more superficial and thought to be less harmful.

Ankle applications

Some surgeons will use standard-sized probes for ankle procedures. Others may choose only small diameter probes like the monopolar Ablator 2mm or the monopolar Micro Ablator. Common ablation uses in the ankle include:

- Excision of scar tissue
- Synovectomy
 Removal of inflamed synovial lining
- Debridement of tendons or ligaments

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New 3.51 Software for Saphyre

The Vulcan generator is a software-driven system that allows us to perform field upgrades. This helps to enhance our competitive edge and keep Vulcan performance completely up-to-date in a cost-effective manner. The upgrades are performed using a PCMCIA card that takes only a few minutes for our field representatives to install. The upgrade process gives you another reason to be in front of your customers to discuss the Smith & Nephew EAS system - and an opportunity to turn this call into a sale!

In the past, ORATEC has had optional upgrades at times that allowed customers the choice to include some additional features. Other upgrades are mandatory; in these cases the software upgrade must be implemented on all Vulcan units to provide for some feature or performance factor that we want to make available to all customers.

Smith & Nephew is pleased to announce the release of version 3.51 software for upgrading the Vulcan generator. Version 3.51 software has many value-added benefits including the ability to use the Saphyre bipolar probes.

This upgrade is <u>mandatory</u> so every generator in the field must be upgraded by the distributorship.

What 3.51 software does for your customer:

- Auto-probe recognition allows the system to automatically recognize the Saphyre models of probes
 - Sets the correct Preset for each probe type.
 - Automatically changes the generator to bipolar mode ("Bipolar" will be illuminated).
- Updates default settings for Ligament Chisels to 90W Cut and 40W Coag (previously was 80W Cut and 40W coag). (Also available in 3.50 software)
- Adds a safety feature for low impedance, monopolar cutting conditions. When the generalor detects impedance below 400 ohms for a continuous 5 seconds, power is rapidly cycled from full to no power until the impedance rises above 400 ohms. This limits the dispersed current to minimize undetected, incidental heating. (Also available in 3.50 software)

Mandatory Upgrade Implementation:

Software upgrade training packets will be sent to each Smith & Nephew Endoscopy field representative including upgrade instructions, reporting instructions, and return instructions.

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An allotment of 3.51 software cards will be sent to the Distribution Executive main office, to be divvied up appropriately amongst the field reps. As the software cards are used up and when reporting information has been returned to Smith & Nephew, an additional quantity of software cards may be requested by the distributorship until all upgrades have been completed throughout the field. No software cards will be sent if reporting information is not received. A detailed tracking program is maintained in-house to ensure that all generators in your territory are upgraded.

How to upgrade software (see the "Upgrading the Vulcan Generator" attached for detailed instructions):

1). Turn off power to the generator.

2) Locate the plate and screws that protect the slot for the software card (located at the bottom, right hand corner of the box).

3) Unscrew the plate protecting the software card slot.

4) If an old software card is in the slot, push the black button located at the left of the card to eject the old software card (ignore this step if no card is present in the slot). Insert the new card into the slot with the label facing down. Make sure the card is securely inserted or the generator will not function.

5) Replace the plate protecting the slot for the software card.

 Turn on the generator and check the LCD screen to make sure that 3.51 software version is displayed.

7) The upgrade is now complete.

8) Complete your paperwork with log account name, date, serial number, etc.

9) Give a copy of the 3.51 software preset table to the customer.

10) Ship any old software cards to Smith & Nephew at the address below. These cards are valuable!

Remember: Once 3.51 software is installed, when using a Saphyre probe check to make sure the box is showing bipolar mode and the correct preset is displayed (Preset 17: 120 cut, 50 coag).

Important Contacts:

- For problems upgrading the software, contact Joan McCreary at 888-996-1996 immediately.
- For additional 3.51 software card shipments, contact Customer Service at 888-996-1996
- Ship old/unused software cards to: Monica Allgood
 Smith & Nephew Endoscopy
 3700 Haven Court
 Mento Park, CA 94025

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Upgrading the Vulcan Generator

Step 1

Prior to upgrading the software:

Turn on the generator and record the software version.

Record the unit's serial number and location.

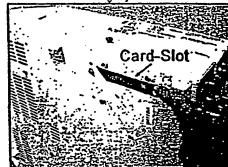
Turn off and unplug the generator. .

Step 2

Remove screws from bottom of Vulcan Generator unit to access the card slot.

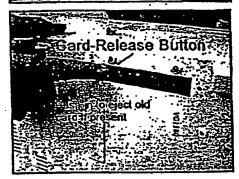
You will need a Phillips screwdriver.

Accessing System Software



Step 3

If a card is present, push the eject button at the front side of the slot. The card will pop free, then remove it. If a card is not present, go to Step 4



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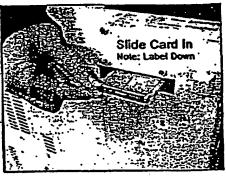
Step 4

Insert the new software card, with the label facing downward. When fully inserted, the card will lock into place. Leave the card in the slot.

Step 5

Once the new card is in the slot, close the card access door and lighten the screws.

Turn on the generator and confirm the display reads Software Version 3.51.



Complete your paperwork and move on to the next generator

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Competitive Overview

Parameter .	ArthroCare	Mitek	Stryker	Linvated	Smith & Nephew- ORATEC
Generator	System 2000	VAPR	Serfas	WA	Vulcan
Market	51%	21%	1%.	1%	26%
BF Ivne	Binolar	Bipolar	Bipolar	Monopolar	Monopolar and Bipolar
Probe groups	Ablation Small joint Shrinkage Suction	Ablation Small Joint Shrinkage, Suction	Ablation Small Joint	Ablation Smell Joint	Ablation Small Joint Shrinkage w/ temp. control Hip
Probe group prices	Ablation-\$151 Small Joint-\$151-156 Thermal modification-\$270 Suction-\$172	Ablation-\$149-161 Small John-\$161 Thermal -\$199-205 Suction-\$154 Temp. Control-\$313	Ablation-\$165 Small Joint	Ablation-\$85 Thermal modification	Ablation-\$129-151 Small Joint\$140-149 Temp. control-\$289 Hip\$450-499
Features	Aggressive.soft itssue resection Multiple tips Perceived large market share in ablation Hand control attachment	Multiple tips Wide range of arthroscopic products Weil known in orthopedic market TC Electrode monitors power output Has probe recognition	Hand control Bendable probes Ability to bundle with other products Well known sales force	Mulliple probe tips Broad line of arthroscopic products Resection/ ablation probe	Very aggressive ablation performance Alkin-one system integrated cable Unique efectrode design Wide range of arthroscopic repair and resection products
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S + N RF Probe Possible Cross Reference

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been verilled on 2:04:02 as current	Smith • Nephew Description TAC-8	TAC-S Angled	TACCI	Saphyre 90 * Bipolar Abiator	Ablater 90°, Monopolar	Ablator 90" HP	Ligament Chisel, Angled	Ligament Chisal, Straight	Abiator 90°	Ablator 30*	Ablator 30*	Ablator Hook	I in Chisel. Cvd.	Ablator 90*	Abator 30° or Ablator 60° 920003	Saphyre 90 * Abtelor, w/Suction	Ablator-S. 90°	Bipolar Ablation Probe. 60°	Ringtar Attlation Probe, 60° w/suction	Ablator 60°, Monopolar	Albator-S. 60*	Micro Ligameni Chisel, Curved	Micro Linement Chisel, Angled	Ariator 2.0mm, 60° Tio	Ablator 2 from 60° Tip. w/Subiton	Ringler Atteiton Probe 90°. High Profile	Melder Att Probe 80°. High Profile withouten	ANAIN OF High Profile	ANATO 90º High Profile-Suction	
I prices have	S+N 921001	921000	921013	925001	920001	\$20007	923002	923001	920001	020002	020002	922004	00000	920001	920002	925011	920011	925003	925013	92003	920013	923006	923005	020023	020014	028007	026016	00000		21007
Note; Milek's current price Itst is dated 2001 but prices have been verified on 2.04-02 as current	Milek description VAPH TC Electrode (2,3mm)*	No comparision	No comparision	Sirle Filect Flectrode (3.5 mm)	Cide Filect Flectrode (3.5 mm)	the compared of		NO COMPLIANCE	No companiero	Angled Side Ellect Electrone (21, 3,3 mm)		Angled End Ellech Electrode (41 , 3.5 mm)	90" Hook Electrode (3.5 mm)	No comparision	Flox, Side Effect Electrone (5:50mm)	Flox End Ellect Electrode (J. Shirth	90 deg. Suchon Eracuode (Johns)	90 deg. Suction Electrode (J. Mint)	No comparision	No comparision	No compansion	No companistan	2.3 Side Effect Electrode	2.3 End Elleci Electrode	Wedge Erectrode (21°, 2.3mm)	No comparision	No compartsion	No comparision	No comparison	No compariston
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Catalog #	ArthroCare Description	Cat, No.	Smith + Nephew Description	Usi Price	List Price
A 1326.01	2.5mm 90° Right Angle	920001	Vulcan Ablator 90, 3:0mm	151	129
A 1330-01	3 Orren 90' Right Angle	920001	Vulcan Ablator 90, 3.0mm	151	129
A 1335-013	3.5mm 90° Right Anale	920007	·Vulcan Ablator 90 HP	151	129
A 1336 01	3.6mm 90° Lo Pro Right Angle	920001	Vulcan Ablator 90, 3.0mm	151	129
A 1345-01	4 Sorm 90° Eliminator	920001	Vulcan Abiator 90, 3.0mm	131	129
4 3525.01	2.5mm 60° dome	820003	Vutcan Ablator 60, 3,0mm	151	129
A 3625.01	2 Som 30 dome	920002	Vutcan Ablator 30, 3.0mm	151	129
10.0230.4	The state of the s	920003	Vuican Ablator 60, 3.0mm	151	129
4 3530°0 €	John 44 have	K/Z	(Bend Ablator 30° to 45° for equal)	151	129
10000 V	1.00m And hevel	921003	Vuican Ablator 60, 3.0mm	151	(29
A 2630.0	a Contract of the Contract of	200026	Vulcan Ablator 30, 3.0mm	. 151	129
NA AN	2.0mm 60° Ablator	920023	Vulcan Zimm Ablator Probe	Y N .	139
	Thermal Drohee (nois: Acare does not control power or lemberature)	uol power or le	mperature)		
	1 Own CARRING	921008	Vulcan TAC-S Probe	270	299
		. 921008	Vulcan TAC-S Probe	270	289
100000		921004	Micro TAC-S	270	299
10-02-1		921009	Micro TAC-S. Angled	Y X	299
X :		921008	Vulcan TAC-S Analed	YN.	299
S		921003	Vutcan TAO-C II Probe	ž	299
Y		20100	Videan MinITAC Probe	ž	299
Š		221004	Videan MicroTAC-8	Ž	28
V		921009	Vutcan MicroTAC-8, Analed	ž	299
₹				•	
	Small Joint Probes-Ablation/Resection			į	•
A 2723-01	2.3mm 25° bevei	923005	Vuican Micro Ligameni Chiser, Ang.		67.
A 2823-01	2,3mm 35° bevel	920005	Vincan Micro Apraior Zumm, 60		2 6
A 1116-01	Microbiator*	923008	Vulcen Micro Ugament Chitel, Hook	2	62 5
¥	N/A	823008	Vulcan Micro Ugameni Chisel, Cvd.	Ž	2
•	Hip Arthrescopy	413007	Videan Effex Lloameni Chieel	¥¥	349
X	:	910014	Vulcan Effex Ablator	X	38
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499	5 5 5	159 172	172	22.5	. 272	27.	<u> </u>	122
165 165	151	172	22	221	2 2 2	22.	2 5	12
Vulcan Ellex TAC·S Vulban Ablalor·S 90°	923003 Ligameni Chisel, CVD 923004 Ligameni Chisel, Hook	-				<i>)</i> 0,		Yulcan Abalor:S, 60* Saphyre Bipolar:S, 60*
911007	923003 923004	920013	920013 _. 925013	920011	920015	920013	920013	910013
WA MuliNac XI.	Cutting Probes CoBlade Saber	Suction Probes 3,0mm 60° CoVac	3.0mm 70°CoVac	3,0mm 90° Tubo Vac	AS 1337-01 3,5mm 90° Turbo Vac HP	Maivec Tribiar 15	Munivac Trisler 50	Than 80
N/A . AS 4730-01	A 4030-01 A 4330-01	A8 2630-01	AS3730-01	A\$1335-01	AS 1337-01	A8 4130-01	AS 4630-01	AS 6640-01

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Competitive Review-Arthrocare

Arthrocare System 2000

Features:

- Single display for ablation and coagulation
- Bipolar system
- Ablation settings 1-9. Settings correspond to these powers:
 - 1-40W
 - 2-50W
 - 3-80W
 - 4-100W
 - 5-125W
 - 6-160W
 - 7-200W
 - 8-240W
 - 9-280W
- ArthroWand Probes
 - Over 25 probe tip styles including ablation, shrinkage, small joint, and suction (ex: MultiVac, CoVac, Razor, Eliminator, CAPSure, Saber, etc.)
 - 90° ablation probes represent the majority of probe sales
- Perceived as having the largest RF market share in ablation business
- Multi-electrode abiation design
- Autoclavable cable -
- Foot and hand controls available



Pricing:

Pricing:		•
System Component	Description	Price
Arthrocare System 2000 (includes Generator, Cable, Foot Control, Power Cord, and User's Manual)	Bipolar generator designed for use with ArthroWand for resection, ablation, and coagulation of soft tissue. Includes nine presets for different probes.	\$7,500
Arthrowands	A wide range of probes are available for ablation, coagulation, and modification of soft tissue	Abiation-\$151 Small Joint-\$151-156 "Shrinkage"-\$270 Suction-\$172

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Cable	To connect the ArthroWand to the System 2000	\$500
Power Cord	Connects the System 2000 to the power outlet	\$100
Probe Bender	Bends malleable probes	\$100
Foot Control	Provides control to the generator with ablation, coagulation, and ablate adjuster	\$750
Hand Switch Control	Same as foot control but accessible by hand	\$300
Cable O-ring	To ensure good connection with Wand and cable	\$10 (pack)

Strengths:

- Aggressive soft tissue resection and coagulation: Very aggressive ablation and good coagulation reduces OR time for the surgeon.
- Multiple tips allow access for many applications that include resection, coagulation, and modification of soft tissue.
- Is the perceived leader in the ablation market, with a market perception of ArthroCare having aggressive ablation.
- Hand and foot controls provide a convenient level of control for power settings and energy activation.

Weaknesses:

- No temperature control to monitor depth of tissue effect that is very important for procedures such as capsulormaphy and chondroplasty.
- Non-specific power settings deny the user a full understanding of the energy being applied.
- Inadvertent heating of surrounding tissue due to concentric, uninsulated return electrode. Users may be confused by the multi-pin electrode configuration and mis-understand potential heating concerns.
- Reaches very high temperatures, as seen in surgery with boiling saline (100°C) and tissue char (-270°C). Overheated fluid may inadvertently damage surrounding tissue in the joint or instrument portal.
- Few malleable probe designs, limiting the ability to access hard-to-reach anatomy (such as posterior hom of the meniscus)

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- 6. No probe recognition, generator does not adjust to each probe for optimal performance, but instead needs circulatory staff to remember and/or adjust settings wasting valuable OR time.
- 7. Autoclavable cables that cause needless delay because of sterilization and bad connection caused by wear. AnthroCare typically charges for replacement cables.
- 8. Generator is not field upgradable possibly leading to down time for shipping or exchanging for a new generator.

Competitive Strategy:

- 1. With the addition of bipolar ablation, Vulcan now offers the best of both worlds: temperature control for temperature sensitive procedures and aggressive ablation to reduce procedure time.
- 2. Vulcan is also teamed with the widest variety of probes including ablation (monopolar and bipolar), temperature control, small joint, cutting, and hip probes.
- 3. With the versatile performance of the Vulcan generator and the scientific data to back its safety and efficacy, Smith & Nephew will be knocking away at Arthrocare's RF market share.
- 4. Sales representatives can use their wide range of Dyonics products to leverage the Smith & Nephew RF products, using its leadership position in the resection market to solidify the relationship.
- 5. Expose the differences in return electrode configuration between Saphyre probes and the Anhrowands.

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Competitive Review-Mitek

Milek™ VAPR™ II (Ethicon Division of Johnson & Johnson)

VAPR II Generator

Features:

- Dual display for ablation and coagulation
- Bipolar system
- Programmable temperature settings
- Temperature Control Electrode
 - Uses thermistor to monitor temperature
 - Software is not as advanced as Vulcan in adjusting output for temperature
- Multiple probe designs for different applications (see following chart for probes and defaults)
- Weak competitor in RF market
- Autoclavable cable
- Foot control



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Pricing:	· Description	Price
System Components VAPR II	Bipolar generator designed for use with VAPR II electrodes for resection, ablation, and coagulation of soft tissue. Includes multiple default settings for various probes.	Not published
VAPR Electrodes	A wide range of electrodes are available for ablation, coagulation, and modification of soft tissue.	Ablation-\$149-161 Small Joint-\$161 Shrinkage-\$199-205 Suction-\$154 Temp. Control-\$313
VAPR Handpiece	Cable to connect the VAPR II to the electrode, recommended for 20 uses.	
VAPR Footswitch	To energy delivery from	\$465

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	VAPR generator	
VAPA Power Cord	To connect the VAPR generator to a power . outlet	\$117
VAPR Sterilization Tray	For sterilizing of reusable product	\$244

Strengths:

- 1. Multiple tips for a wide range of applications including resection, coagulation, and modification of soft tissue.
- 2. Wide range of orthopedic products to leverage relationship with customer.
- 3. Well-known name in the orthopedic market.
- 4. TC Electrode that monitors temperature for temperature-sensitive procedures.
- 5. Generator is programmable for probe-specific default settings

Weaknesses:

- 1. Average tissue response to electrodes, slowing down the procedure.
- 2. Limited availability in probe designs that allow access to hard-to-reach places.
- 3. Autoclavable cables that cause needless delay because of sterilization and faulty connections caused by wear.
- 4. Power settings are not refined with accurate temperature control to provide consistent performance.
- 5. Generator is not field-upgradable, possibly leading to down time for shipping or exchanging for a new generator.

Competitive Strategy:

- 1. The best way to combat the Mitek product is to show the complete package that we offer with the leading temperature control product on the market along with aggressive monopolar and bipolar ablation. No other company can offer that
- 2. Team the all-in-one system with the leading resection products of Smith & Nephew and you have a winning combination.' Even with Milek's range of . products, we provide the most comprehensive line of products with superior quality and service.
- Make a clear distinction between Vulcan temperature control and VAPR temperature control. Vulcan uses a thermocouple to measure temperature at the probe tip and adjusts the power output 50 times a second! The Vulcan software also has other key technology built into the generator to optimize

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performance while keeping accurate temperature control. For example, ramping the power up quickly when the footpedal is depressed to reach the target temperature quickly, then backing off the power as the temperature is reached to maintain an even temperature level. This way the generator only delivers the minimum power needed to maintain tip temperature. Mitek uses a thermistor to measure tip temperature and the software used in the VAPR generator is not as advanced as the Vulcan.

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Competitive Review-Stryker

SERFASTM System

Features:

- Single display for cut with presets. Low, Medium or High settings for coag.
- Bipolar system
- Built-in troubleshooting guide with voice feedback
- SERFAS Probes
 - Seven probe styles for ablation including two small joint probes
 - Malleable up to 45^s
 - Flow-Port™ to reduce bubble size (no suction)
- · Hand and foot controls
- Autoclavable cable .

Pricing:

Ablation probes-\$165

Strengths:

- 1. Hand and foot controls to allow the surgeon to adjust the settings easily.
- 2. Bendable probes to allow better access to joints.
- 3. Ability to bundle the probes with other arthroscopy products.
- 4. Well-known sales force.
- .5. Troubleshooting guide built into system.

Weaknesses:

- No temperature control probes for contraction of soft tissue or cartilage applications (using bipolar ablation on cartilage has been shown to have a much greater depth of penetration than monopolar TAC-C II probe).
- 2. No scientific data on tissue effect.
- 3. Average ablation performance.
- 4. Only seven probe styles, limiting applications and choices for the surgeon.
- 5. No suction probes to reduce cloudy or "snowy" field.
- 6. No probe recognition, the circulator must adjust the settings.
- 7. Limited power settings for the surgeon, reducing versatility of probes.
- 8. Autoclavable cables that cause needless OR delay because of sterilization and bad connections caused by wear.

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- 9. Generator is not field-upgradable, possibly leading to down time for shipping or exchanging for a new generator.
- 10. Late entry to RF market with very small market share.

Competitive Strategy:

- 1. SERFAS is no contest for the comprehensive Smith & Nephew line of probes, which has over 25 probe styles that include ablation, temperature control, monopolar, and bipolar capabilities.
- 2. Point out Vulcan's extensive data to show tissue effect compared to Stryker's lack of data.
- 3. Use your superior line of Smith & Nephew products including the #1 resection products in the business to combat Stryker's bundling.
- 4. Vulcan's comprehensive, easy-to-use system with integrated cable and autoprobe recognition gives the physician a user-inendly, flexible choice compared to the SERFAS. Vulcan also has live 24 hour support for troubleshooting needs.

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Competitive Review-Linvatec

Generator and Probes:

- May be used with many standard monopolar electrosurgical generator (ex: Valleylab, Conmed)
- Attaches to bovie pencil handle
- Variety of probes for ablation, cutting, and coagulation (UltrAblator™, Trident combination ablator/shaver, Heatwave™, Concept®, ESA)
- Uses "coag" mode for ablation, "cut" mode for coagulation, and "cut" mode for capsular shift

Pricing:

System Component	Description	Price
Generator	Produces power output to run probes. Many standard electrosurgical generators work.	Relies on having an electrosurgical generator in the facility. Prices vary.
Electrosurgical Product Line	Includes a limited mix of probe tips for ablation, coagulation, cutting, and capsular shifts	Ablation-\$85 Shrinkage-unknown
Grounding Pad	Needed for use with electrosurgical generators	-\$6-10

Strengths:

- 1. Multiple probe tips.
- 2. Broad line of arthroscopic products.
- A unique shaver/ablation probe called Trident.
- 4. Trident incorporates suction through the shaver blade opening.

Weaknesses:

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- Average performance.
- 2. Limited probe tips that may not fit surgeon preference.
- 3. No temperature control to control depth of penetration during capsular shifts.
- 4. Has to rely on functionality with other manufacturers electrosurgical generator for probes to work.

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- 5. Trident's suction is not at the point of ablation, which may inhibit removal of bubbles from the point of energy delivery.
- 6. Autoclavable cables that may delay surgery due to bad connections or need for sterilization.
- 7. No scientific data to show tissue effect.
- 8. Most probes are very similar to bovie pencil that the accounts already have.

Competitive Advantage:

- 1. The best way to combat Linvatec is to ask the surgeon to use the product (especially works for the Trident). Reports from the field say it has mediocre ablation and coagulation performance compared to Vulcan's monopolar or bipolar ablation, and coagulation doesn't stand a chance. The surgeon probably won't want to use it again.
- 2. If the surgeon is motivated to use Linvatec because of bundling programs even though performance isn't great, use our superior line of products to offer a better value to the surgeon. We have the tools available with the quality and performance they want. And we can offer bundling with Dyonics equipment, too. ·
- 3. They have no temperature control for capsular shift procedures to control heating of tissue, we do. This is key in capsular shift procedures for optimal
- 4. We have extensive data that shows tissue effect with Vulcan products; point out Linvatec's lack of data.
- 5. The inability to customize setting and limited probe tips severely limits the surgeons' choices with the Linvatec line. Vulcan is able to give the surgeon a wide variety of probe choices with the most up-to-date software for each probe. The Vulcan system can do it all.

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Competitive Review: Probing Questions

Use the following probing questions to get your customer thinking about the advantages that the Saphyre probe and Smith & Nephew EAS can offer. Questions can lead your doctor to the make the purchasing decision on his/her own.

- 1. What factors are important to you in selecting an ablation probe? If our product could meet your objectives, would you evaluate it?
- Would you see an advantage to using a sole source supplier for arthroscopic resection? Would having to work with one sales representative ease congestion and disruptions in the OR?
- 3. Is there ever a problem with locating or using re-usable cable in the OR? Would eliminating a piece of equipment help to control OR efficiency?
- 4. Are you satisfied with the level of control that you obtain with your current bipolar product?
- 5. Have you ever wanted to switch between ablation and temperature control probes in a case, but this was difficult because you use two different vendors with different generators?
- 6. How often is the return electrode of your current bipolar ablation probe outside of your field of view while you are ablating?
- 7. Have you ever wondered what is happening to the lissue that the return electrode is touching while you are ablating?

Be prepared to handle objections from the surgeon. Here are some examples.

1. Doctor: I'm happy with my current bipolar probe's ablation performance.
Why should I switch to your bipolar probe?

Product. The return electrode is here, just below the tip. Notice how the electrode wraps around the front and sides, but is insulated on the back, protecting adjacent tissue. Now look at the bipolar probe you are using. The return electrode is also just below the tip, but it wraps around the entire shaft. This can expose tissue like the rotator cuff to a very hot surface when ablating in the subacromial space.

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My surgery center is very cost-conscious. I'm not sure I like the Doc: pricing you're offering.

Doctor, I can offer your hospital a nice pricing and service advantage if you choose Smith & Nephew as your sole source Rep: provider of resection products. Since you're already a great Dyonics shaver customer, it would be a natural to bring Vulcan and Saphyre products into your surgery center. From a cost perspective, you have a fantastic opportunity here.

I don't use RF ablation very much. Why should I change my Doc: current practice?

Rep:

What is your current method for resection procedures? If you use Dyonics equipment and you are happy, there's no reason to change. However, Smith & Nephew now offers an extensive line of RF arthroscopy probes for a variety of applications. Your colleagues may also benefit from the small joint and hip probes. I would be happy to contact them and let them know about this new opportunity.

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Using the Vulcan customer list and our targeted launch strategy for the Saphyre line, it should be relatively straightforward for you to identify the appropriate clinical decision makers to approach with Saphyre probes. It will be very important for you to avoid simply pulling Saphyre probes out of the bag and showing it off. Use your selling skills to gain an understanding of your customer's needs and objectives relative to RF systems before you actually present the Smith & Nephew EAS and Saphyre probes.

Please don't forget that each OR has a variety of decision makers, including the surgeon, nurses, OR supervisors and purchasing personnel. Position yourself as a resource with all of these parties to maximize your influence during the sales process.

The outline below walks through an effective sales process that may transpire on one visit or over several calls on this customer. The bullet points with quotes will give you some examples of useful lead-ins or wording that may be helpful to you. Other lines of questioning may be appropriate for your customers. You can use the following structures with any of the selling strategies outlined earlier in this Sales Guide.

Opening the Sales Call

- Ask questions to investigate whether this is an appropriate time to dive into the topic of RF.
- Position the current sales call to gain the customer's attention.
 - > "When I was in last week you mentioned that you would be interested in discussing RF in arthroscopy with me, at some point in the future. Would this be a good time for that?"
 - Over the past few visits, you and your staff have expressed concern over the increasing amount of equipment and confusion amongst the OR staff over having different systems for RF: May we discuss this further?"

Focus on the Customer's Situation

- Begin to focus your customer on the topic that you plan to discuss.
- Probe the current situation and methods used by your customer further.
- Use questions to uncover your customer's thinking and feeling!

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- "I've noticed that you have more than one RF arthroscopy system here in the OR. Why is that?"
- "Bring me up to date on your use of RF in cases here at Mercy. How has RF been incorporated into your practice?"

Explore Your Customer's Problems and Objectives

- · Follow the issues your customer brings up during your discussion of the current situation.
- Structure questions to explore problem areas that we expect to be occurring.
- Questions also can reveal the objectives your customer may have to resolve current problems.
 - > "Have you ever had a case delayed because a circulator was not familiar with the various RF generators in the OR?"
 - > "How have you responded when the connection cable between RF probe and the generator is not ready to go or is not in the room?"

Investigate and Reveal the Implications

- Now that you have an understanding of some of your customer's problems, formulate questions to reveal the underlying implications.
- . The issues uncovered by exploring problem implications help to expose the problem further - making it more urgent for the customer to act to solve the problem.
- · Your questions can reveal problem implications that Vulcan and Saphyre products can clearly solve!
 - > "Having multiple RF systems here at Mercy does seem difficult. How have these delays affected your practice?"
 - *OK, so your staff is tired of keeping up with all of the connection cables. How have the connection cable problems affected your use of RF in these cases?"

Develop Your Customer's Needs

Use the problems and implications you've uncovered to develop a customer need that the Smith & Nephew EAS can resolve.

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- * Ask questions that will reveal a need-payoff that Vulcan can provide.
- Begin to position your product offering as the solution to your customer's needs!
 - > "Dr., would it be valuable to you to consolidate all RF use in one system? If I can show you that the Vulcan generator can excel at both temperature control and ablation, would you be willing to consider consolidating your RF usage?"
 - > "Would you be interested in evaluating a system that eliminates the connection cables? What would you do with an ablation system that eliminated the connection cables?"

Ask for the Order!

- By following the sales process outlined above, you now have the customer in position to ask for an appropriate order or commitment.
 - > "You already have the Vulcan generator here in your OR, let me bring in a sample ablation probe for you to evaluate during your next case. How about tomorrow?"
 - > "You and your staff will love the Integrated Cable probes. When, is your next case that will use RF ablation, and I'll be here with some evaluation probes?"

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Selling Tools and Resources

See the Price List in the Collateral Materials Section.

Our price schedule for the Saphyre line places it in direct competition with ArthroCare and Mitek. With the features and benefits offered by the Saphyre line and the Vulcan generator, you should not have a large pricing hurdle to overcome. The key to success with this product is to sell the system and its teatures and benefits!

Discounting:

There is no standard discount available for Saphyre products.

Please review the attached price list and be ready to share this information with your customers.

Customer Targets

We are providing your distributor executive's office with information about current Vulcan customers that use our temperature control (TAC) probes, but do not order monopolar ablation products. These customers will form your top-priority account group. All of these customers have Vulcan generators in place and nearly all of them can be expected to have substantial volume in ablation probes.

The accounts on this report will be your top priority!

Saphyre Line Launch Roll-out

Each sales agent will receive four demo probes after the Knowledge Assessment is returned (enclosed). Smith & Nephew sales management will conduct frequent reviews of the Saphyre probe sales to ensure that appropriate accountsare being targeted and that monopolar ablation accounts are not cannibalized.

Saphyre Line In-service

See the Saphyre probe instruction for Use (IFU) for more details.

Ordering Information

Order Saphyre Bipolar ablation products using the Smith & Nephew West Coast Customer Service line: 888-996-1996

Be sure to specify model number or complete description and quantity for each item ordered.

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· Identify product and packaging

- Identify the packages containing Saphyre bipolar probes by:
 - > Gray color band on labels (vs. black for monopolar ablation)
 - > Label says "Saphyre"
 - > Model numbers: 925XXX
- Identify the product after opening the package by:
 - > Gray color insulation on probe shaft.

Pre-procedure prep issues

- Prior to any procedure using Saphyre probes, the software of the Vulcan generator must be upgraded to version 3.51 or higher. The current software version of each Vulcan generator is displayed in the LCD message window when the generator is first powered up. A Vulcan with any software revision prior to 3.50 will not operate a Saphyre ablation probe.
- The Vulcan generator should be placed in a location close enough to allow probe connection (usually within 10 feet of the table).
- If it is possible that more than one probe will be used by the surgeon, or it is unclear which probe tip style will be used, make sure all of the appropriate probes are available in the room before the case begins.
- If the case has a chance of including the use of temperature control (TAC) probes or other monopolar probes, apply a Valley Lab grounding pad (split-pad return electrode) to the patient before draping the patient.
- The Saphyre bipolar ablation probes require the use of a conductive irrigation solution. Saline or Lactated Ringers solutions are good choices.

Probe selection

- Tip configuration the Saphyre line is available in 3 tip configurations:
 - 90-degree
 - 90-degree high profile
 - 60-degree
- Suction vs. non-suction each Saphyre tip configuration is available in a non-suction model and suction model.
- Each surgeon will determine which model to use based upon the patient's anatomy, type of procedure and personal preference.

Connection to generator

- The scrub tech in the sterile field can remove the clips that bundle the integrated cable of the Saphyre probe.
- The scrub tech passes the connector-end of the integrated cable to the circulator outside the sterile field.

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The circulator connects the Saphyre probe cable to the Vulcan and turns the power on.

That's it! The Vulcan generator will recognize that a Saphyre probe has been attached and set the appropriate operating parameters (pre-sets). The system is now ready to operate!

Saphyre probe use tips/techniques

NO Bending of probe shaft - Saphyre probe shafts are not maileable. The probe bender should not be used to modify the shaft shape.

The surgeon may ask for the power levels to be adjusted during the case. Using a Saphyre probe, the Vulcan generator may be manually adjusted between 5 and 160 watts for both Cut and Coag modes.

 Care should be taken to prevent tissue contact with the return electrode on the Saphyre probe shaft. While it will not be as hot as the active electrode at the distal tip, the return electrode may become heated. For this reason, it is important to avoid inadvertent contact with tissue adjacent to the operative site.

Full tissue contact may not be required during Cut or Coag applications. Saphyre probes may perform to the surgeon's clinical requirements when the probe tip is in close proximity to the tissue.

Power delivery to the probe when the probe is not in tissue proximity (that is, foot pedal activation when not actively ablating or coagulating) risks increasing the temperature of the fluid in the joint. Be careful to terminate power delivery and to increase flush rate when possible.

Probe disconnection and disposal

 When use of the probe is complete, disconnect the integrated cable at the Vulcan generator.

Discard the entire probe with its cable. Usually a contaminated sharps container is an appropriate disposal container.

Please see the Saphyre probe Instruction for Use (IFU) for more details.

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ORA 0052414

From: Joan McCreary [imccreary @oratec.com]

Sent: Wednesday, May 01, 2002 11:19 AM

To: Peggy Greene

Subject: Saphyre collateral materials

Joan McCreary
Product Manager, Anthroscopy
Smith + Nephew, formerly ORATEC Interventions, Inc.
Endoscopy Division

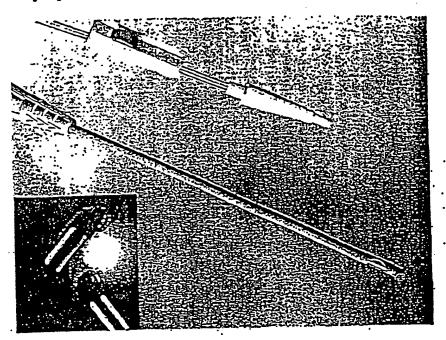
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> > ORA 0052431

6/20/2002

Suphyre" Bipolar Ablation Probes



l ekab

60°, 90° and 90° high profile tips in suction and non-section styles

Jamel-cut electrode for rapid ablation and precise coopulation

Integrated cable simplifies Q.L. setup

Suction regulator provides adjustable Bow control for excellent visibility

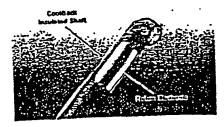
Bipolar Ablation with Unique Features for Performance and Convenience

Saphyre" Biploar Ablation Probes offer a new standard for tissue removal. The jewel-cut notched electrode directs energy where it is needed to maximize tissue effect. The result is a larger area of tissue effect with rapid ablation. Saphyre probes incorporate the CoolBack" shaft design, which protects adjacent tissue by not exposing the return electrode on the posterior shaft. As with all Smith & Nephew probes, the Saphyre has an integrated cable which takes the cable resterilization and storage off the Q.R. checklist.

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SmithNephew

ORA 0052432





Coolback, shak insulates callateral vissue on both section and non-section styles

Saphyre Bipolar Ablation Probes

Ordering Information

REF	South & Haphow REF	Description .
723001	7207686	Spoke Allesia Probe, 90"
121011 .	7209443	Sipolar Alderica Probe, 90° with Section
125003	7201485	Spaler Alderina Probe, 60°
723013	7201443	Ripcler Allerien Probe, 60° with Section
123007	7207484	Spoke Alician trobe, 10° Eigh trolle
725018	7201481	Spaler Milation Probe, 90° Sigh Proble with Section

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Smith**⊕**Nephew

www.endescopyl.com

Smith & Nephew, Inc., Endoscopy Division Menio Park, CA, 94025 U.S.A. Telephone: 650-369-9904 · Fax: 650-369-9913 U.S. Castomer Service: 1-188-996-1996erantional Customer Service: +1-450-369-9994

Outside the U.S., please connect an authorized representative of Smith & Nephew.

For consistent, repeatable ablation results, choose Saphyre Bipolar Ablation Probes only from Smith & Nephew, a world leader in technique innovation for endoccopy. Our strategic intent is to be: The choice of surgeons worldwide for surgical techniques that reduce traums and pain to the potient, reduce cost to the healthcare system, and provide better outcomes for surgeons. Please let us know how we can help you.

Suplyer and Comfflict are undersate of ORATEC transmisses, Inc. O friend on Resychol Paper,

ORA 0052433



U.S. Hospital Price List Smith & Nephew ElectroThermal® Arthoscopy System (EAS®) Effective 04/24/2002

	Coblo	- Unit Price
Catalog #	Probes with Integrated Cable	\$299
921001	TACM-S	\$299
921008	TAC-S Angled	\$299
921013	TAC-C II	\$115
923001	Ligament Chisel ^{D4} Straight	\$115
923002	Ligament Chisel - Angled	3115
923003	Ligament Chisel - Curved	\$115
923004	Ligament Chisel - Hook	
eeee01	Ablator ^{na} 90°. 3mm	\$129
920001	Ablator, 30°, 3mm	. \$129
920002	Ablator, 60°, 3mm	\$129
920003	Ablator, HP 90°. 3mm	\$129
920007	2mm Ablator	\$139
920023		3159
920011	Ablator-S 90°, 3.5mm (suction)	. \$1.59
920013	Ablator-S 60°, 3.5mm (suction)	\$159
920014	Ablator-S 2mm (suction)	\$159
920015	Ablator-S HP 90°, 3.5mm (suction)	·
	in a with Internated Cable	·
Catalog #	Small Joint Probes with Integrated Cable	\$149
920006	Micro Ablator	\$169
920016	Micro Ablator-S (suction)	\$169
920026	Micro Ablator-S High Profile (suction)	\$325
921002	Mini TAC	\$325
921004	Micro TAC-S	. \$325
921009	Micro TAC-S Angled	\$140
923005	Micro Ligament Chisel - Angled Micro Ligament Chisel - Curved	\$140
923006	Micro Ligament Chisel - Hook	\$140
923008	WICTO LIBRIDIC CIDEL - HOOK	•
•	Hip Arthroscopy Probes, requires 8-pin Extension	n Cable.
Catalog #	HID ARTHOSCOPY Probes, requires 5 pm	
910014	Effex** Ablator	. \$49 9
911007	Eflex TAC-S Eflex Ligament Chisel	\$450
913007	Fliex Figativent Curses	•
,		Price _
Catalog #		\$13,495
815000	Vulcan@ Generalor	•
	Includes: footswitch and power cord	
0-4-1c- à	. Accomprise	Price
Catalog i	Accessories Extension Cable* - 8 pin, autoclave, packaged	\$295
815001		\$495
815002	Footswitch HIGHLY CO	NFIDENTIAL \$85
805004	Probe 1 ip Belloci	SEYES ONLY \$6
815019	Split Electrode Pad INFOR	MATION
	• •	<u>.</u>

* Please refer to Sterilization Instructions on last page. Prices Subject to change without notice.

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U.S. Hospital Price List Smith & Nephew ElectroThermal® Arthoscopy System® (EAS®) Effective 04/24/2002

Catalog #	Saphyre Bipolar Ablation Probes	
925001	Saphyre™ 90°, 3mm	\$151
925003	Saphyre 60°, 3mm	\$151
925007	Saphyre 90°, 3mm High Profile	\$151
925011	Saphyre 90°, 3 mm with Suction	\$172
925013-	Saphyre 60°, 3mm with Suction	\$172
925015	Saphyre 90°, 3mm High Profile with Section	\$172

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770103 Rev. 07

ORA 0052435

U.S. Hospital Price List Smith & Nephew ElectroThermal® Arthoscopy System® (EAS®) Effective 04/24/2002

Ordering Information

Orders may be placed with our Customer Service Department:

 Smith & Nephew
 Toll Free:
 (888) 996-1996

 3700 Haven Court
 Telephone:
 (650) 369-9904

 Menlo Park, CA 94025
 Fax:
 (650) 369-9913

Terms

Shipments are F.O.B. Menlo Park, CA. Terms are not 30 days. All purchase orders are subject to acceptance by Smith & Nephew. In the event of conflicting terms, our terms will prevail. Prices are subject to change without notice. All applicable taxes will be added to the invoice. A finance charge may be assessed on all unpaid balances over 30 days at 18% per annum - 11/2 % per month.

Return Policy

Smith & Nephew products received by the customer in damaged or non-working condition may be returned for full credit or replacement within 30 business days from the date of invoice to the customer. Contact the Smith & Nephew Customer Service Department for a Return Material Authorization (RMA) number. Please reference the RMA number on the outside of the shipping carton.

Full credit will only be issued for items returned within 30 days of invoice date, if unused and in the original packaging; items returned after 30 days from the date of invoice may be subject to a 25% restocking fee.

The following merchandise will not be returned for credit:

- Merchandise with broken sterile package seals; used, damaged or incomplete case quantities.
- Special order products.
- Merchandise held past 30 days from invoice date.
- Products not used before the expiration date or the "Use Before Date."
- Discontinued products.

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Smith & Nephew products are manufactured for use by qualified medical personnel who are trained in their use. All Smith & Nephew RF arthroscopy products are warranted to be free from defects in workmanship and materials for ninety (90) days from date of sale. Any Smith & Nephew product with such defect will be repaired or replaced at Smith & Nephew's option, at no charge to the customer. Smith & Nephew shall not be liable, expressly or implied, for:

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 - a. misuse, misbandling, and/or improper operation,
 - repairs or modification performed other than by Smith & Nephew or an Smith & Nephew authorized repair facility.
 - e. use in any manner or medical procedure, other that for which it is designed; and
- Any special, indirect and/or consequential damages of any kind and however caused arising from the sale or use of the products.

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* Sterilization Instructions

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For Extension cable - after proper cleaning.

Pre-vac: Wrapped four (4) minutes pre-vacuum steam exposure at 270-275° F (132-135°C)
Flash Gravity: Unwrapped ten (10) minutes at 132°C (acceptable range 131.5-133.5°C)
For Proximal Proximal Acceptable range (leaving)

For Probe Benders - after proper cleaning,

ORA 0052436

Prices Subject to change without notice.

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770103 Pev. 07

U.S. Hospital Price List Smith & Nephew ElectroThermal® Arthoscopy System® (EAS®) Effective 04/24/2002

Pre-vac: four (4) minutes pre-vacuum steara exposure at 270-275°F (132-135°C)

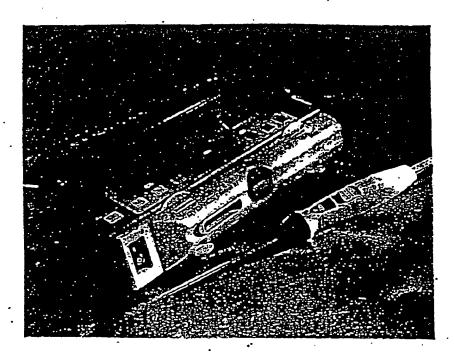
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Dyonics® Control RF System Arthroscopic Radiofrequency System



Sales Guide

Prepared by the Marketing & Sales Training **Departments**

ARTC 05530

Confidential .

Plaintiff's Trial Exhibit PX 593

Chapter 3: Recognizing Potential Customer Problems and Objectives

Categories of Potential Customer Objectives

Technical Objectives

- . Easy to set-up for the OR staff
- Simple to use for both the OR staff and surgeon
- Reliable operation
- · Minimal impact on current standard of care

Economic/Business/Organization Objectives

- Reduce OR downtime/Increase OR tumover
- · Simplify training requirements
- Enhance OR efficiency
- Reduce inventory levels

Medical Objectives

- · Enhance patient outcomes by:
- Reducing the amount of bleeding
- · Improving visualization during the procedures
- Increasing procedural speed to reduce anesthesia time

Customer Service Objectives

- · Reliable operation, minimal need for follow-up service calls
- · Prompt, knowledgeable service and support

Professional/Personal Objectives

- · Cutting edge professional recognition
- Satisfied patients producing subsequent referrals

ARTC 05555

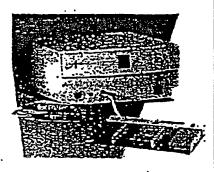
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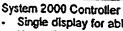
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Competitive Review - ArthroCare

ArthroCare® System 2000

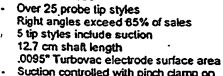
Product Definition





- Single display for ablate and coag
- Non-adjustable 20W coag setting
- Ablate settings from 1 9 1 = 40W
 - 2 = 50W
 - 3 = 80W
 - 4 = 100W
 - 5 = 125W
 - 6 = 160W
 - 7 = 200W
 - 8 = 240W
 - 9 = 280W
- **Bipolar operation**

ArthroWand Probe



- Suction controlled with pinch clamp on tubing
- Reusable handpiece
- 3 pedal footswitch
- Ablate, coag and ablate adjuster

ArthroCare Strengths, Weaknesses and Competitive Strategy

Strengths

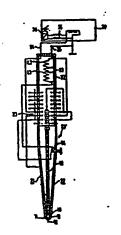
- First to market with bipolar ablation
- Broad product line
- Strong patent position

ARTC 05570

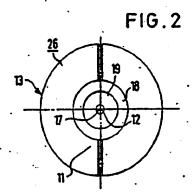
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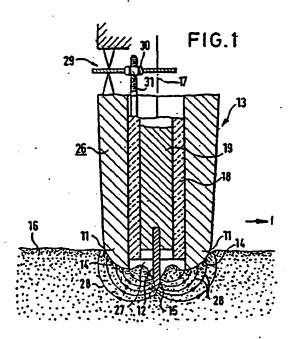
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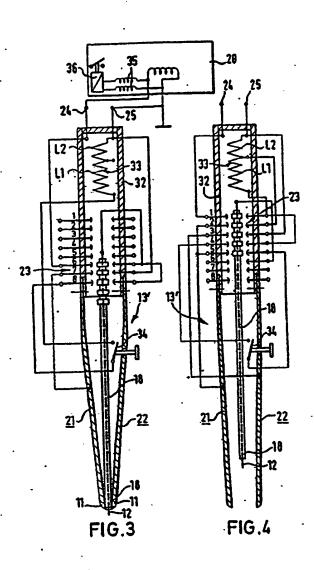
United States Patent (191		[11]	1	Patent l	Number:	4,706,667	
_	Roos		[45]	1	Date of	Patent:	Nov. 17, 1987
[54]	ELECTRO CUTTING	SURGICAL HIGH FREQUENCY INSTRUMENT	3,920 4,013 4,034	, \$7	2 3/1977	Komiya Gosen et al.	128/303.17 128/303.14 121/303.17
[75]	laveator:	Eberhard Roos, Tuttlingen, Fed. Rep. of Germany	4,043 4,202	Ü		Morrison Hrea et al	128/301.14 128/301.14 121/301.14
[73]	Assignee	Berchtold Medizin-Elektronik GmbH & Co., Tuttlingen, Fed. Rep. of Germany	4,274 4,331 4,476	1,41 1,94 6,86	3 6/1981 0 7/1982 2 10/1984	Hake et al Rosso Pao	121/303.17 121/303.17 121/303.17
[21]	Appl No.	: 892,863					OCUMENTS
[22]		Jul. 22, 1986	252 292	171 661	9 11/1976 0 1/1981	Ped. Rep. of Fed. Rep. of	Germany - 121/303.1 Germany - 121/303.1
Related U.S. Application Data [62] Division of Ser. No. 747,016, Jun. 20, 1965.		Primary Examiner—William E. Kamm Austrant Examiner—Max F. Hindenburg Attorney, Agent, or Firm—Townsead and Townsend					
	[30] Foreign Application Priority Data		[57]			ABSTRACT	•
Jua. 25, 1984 [DE] Fed. Rep. of Germany		In an electro-surgical r.f. cutting instrument in which the neutral electrode (11) is arranged on both sides of the cutting electrode (12) but is however set back relative to the cutting electrode (12) on the instrument body (13). The ratio of the sizes of the contact areas (14, 15) of the neutral electrode (11) and of the cutting electrode (12) is greater than 7:1 and smaller than 20:1. 3 Claims, 4 Drawing Figures					



Plaintiff's Trial Exhibit PX 605







This is a division of application Ser. No. 747,086, filed 5 June 20, 1985.

The invention relates to an electro-surgical high frequency cutting instrument comprising a preferably elongate instrument body from which, in the operative state, a small area cutting electrode projects forwardly, 10 and a large area neutral electrode which can be brought into contact with the patient near to the cutting electrode.

In a known electro-surgical high frequency cutting instrument of this kind (DE-OS No. 25 21 719) the 13 neutral electrode is admittedly arranged in the immediate vicinity of the cutting electrode, it is however so separated from the dissue by a plastic cover, or by its arrangement in an endoscope, that it can only enter into electrical contact with the cutting electrode electrolytically via the secretion which is present during the cutting process. As a result, it is difficult to maintain the current intensity required for troublefree cutting in a required precisely defined manner at the cutting electrode. Thus, if the power setting at the 1.f. generator is 25 too high, burns can result or, if the power setting is too low, then a poor cut or indeed injury occurs because the tissue to be cut sticks to the cutting electrode as a result of coagulation processes:

The principal object of the invention is to provide an 30 electro-surgical high frequency cutting instrument of the initially named kind in which current conditions which are largely precisely defined are present at the cutting electrode during the making of a cut substantially perpendicular to the longitudinal axis of the body 35 of the instrument, with the current conditions ensuring a troublefree clean cut of the tissue without overheating of the tissue and without the tissue and the instrument sticking together.

In order to satisfy this object the invention provides 40 that the neutral electrode is arranged on the instrument body on both sides of the cutting electrode, but set back relative to the cutting electrode, in such a way that it is supported on the tissue on both sides of the cutting electrode while the axially projecting cutting electrode 45 pencetrates into the tissue, and that the ratio of the sizes of the contact surfaces between the neutral electrode and the tissue on the one hand and between the cutting electrode and the tissue on the other hand, it greater than 7:1.

If, in a cutting instrument of this kind, a power of for example 5 to 10 Watts per mm2 is applied to the cutting electrode then a power density occurs at the cutting electrode, which is preferably formed as a point, which is such that the heat necessary for tissue separation is \$ generated in the tissue and in the tissue cells. The fact that the neutral electrode itself is likewise in current conducting contact with the tissue ensures a problem free flow of current between the cutting electrode and the neutral electrode. In other words the transition 60 resistance between the two electrodes is substantially constant. As a result of the larger area of the neutral electrode which is in contact with the dissue the power density at the neutral electrode is reduced so far that with normal cutting speeds of the order of several cm 65 per sec. not even tissue beating, which could lead to congulation, occurs. The neutral electrode thus slides smoothly over the tissue during cutting while the cut-

ting electrode, which is arranged directly alongtide or between it, causes the required strong heating at the desired location of the cut that is necessary to execute a smooth cut. As the resistance between the cutting electrode and neutral electrode is largely constant the high frequency power of the generator can be regulated to a value at which overheating of the tissue is also effectively avoided in the area of the cutting electrode, but such that a clean cut is nevertheless obtained.

The radiofrequency cutting instrument of the invention is uncritical in its operation by the surgeon because a problem-free electric cut is effected through the cutting electrode even with irregular cutting speed, withcut tissue damage or adhesion occurring in the region of the neutral electrode.

In order to prevent the cutting instrument of the invention from becoming awkward to handle provision should further be made that the ratio of the sizes of the contact areas of the neutral electrode and of the cutting electrode is smaller than 20:1 and preferably smaller than 16:1.

One obtains particularly good electro-surgical cutting characteristics combined with a compact and slim construction of the instrument body if the ratio of the sizes of the contact surfaces of the neutral electrode and of the cutting electrode is approximately 10:1.

Although the cutting electrode could also have the form of a narrow blade, it is preferred for the cutting electrode to project substantially axially and preferably also in a straight line from the tip of the instrument body. If the cutting electrode is in addition formed with a sharp tip then the power density in the tip region is particularly large which is important for a smooth cut free of injury.

The depth of cut preferably amounts to 0.5 to 5 mm. The extent of the neutral electrode which surrounds the cutting electrode in the direction perpendicular to the zxis of the instrument body preferably amounts from 2 to 6, in particular from 3 to 5 and most particularly to approximately 4 mm.

The cutting speed conveniently amounts to from 1 to 5, in particular from 2 to 4 and preferably to approximately 1 cm/sec.

The distance of the cutting electrode from the nestral cleatrode in the direction perpendicular to the sxis of the instrument body usefully amounts to from 5 to 15 and in particular to approximately 10 sms.

When the cutting electrode has a needle-like tip this tip preferably has a diameter from 0.1 to 0.5, in particular of from 0.2 to 0.4 and particularly of approximately 0.3 mm. The cutting electrode preferably projects an ally beyond the neutral electrode by from 1 to 5 mm.

The tip of the cutting electrode can usefully have a length from 2 to 5 mm and preferably of approximately 1, 3 mm.

As electrical insulation is necessary between the two electrodes a preferred practical embodiment is usefully arranged in such a way that the cutting electrode projects axially from an insulating body arranged inside the nearral electrode.

In order to increase the path for leakage currents between the two electrodes as advantageous further embodiment of the invention is characterised in that the insulating body is set back axially relative to the contact surface of the neutral electrode.

Furthermore, a practical realisation of the invention provides that the insulating body is formed as an insulating sleeve in which a metal sod is located which is connected to the generator and which carries the cutting electrode.

With this arrangement it is also expedient if the motal rod is set back axially relative to the neutral electrode, and preferably also relative to the insulating sleeve, in order to further reduce losses by leakage currents directly between the two electrode

It is of particular advantage if the cutting electrode is axially displaceably arranged on the instrument body. In this way the depth of cut can be preselected by the 10 operator before performing an electric cut, with the range of adjustment being advantageously selectable veca 0.5 and 5 mm

In one realisation of the invention the neutral electrode can be circular cross-section and can concentri- 15 cally surround the cutting electrode. In this case the instrument thus has approximately the shape of a pencil or stylus which can also be correspondingly held and guided by the operator. The metal tip which forms the cuting electrode projects from the bottom of the stylus 20

A further embodiment is constructed so that the se tral electrode is realised by the tips of the two limbs of a pincette or pair of tweezers which forms the insulating body. With this arrangement it is particularly expedient 25 if the insulating sleeve with the cutting electrode can be retracted relative to the limbs of the pincette. In this manner the pincette can also be used without the cutting electrode of the invention.

Finally, this embodiment can be so further developed that the two branches of the pincette are insulated from one another, with a switch being provided which, when the cutting electrode and the insulating sleeve are retracted connects the limbs to the two voltage bearing terminals of the r.f. generator.

As a result of this construction the cutting instrument can also be used for congulation, it being necessary to take appropriate electrical matching measures at the r.f.

In order to ensure injury-free sliding of the neutral 4 electrode on the tissue surface during the cut the contact surface of the neutral electrode should be of appropriate smooth and rounded shape. In particular, the neutral electrode is made of substantially hemispherical rounded shape at its end which enters into 45 contact with the tissue.

The invention will now be described in the following by way of example only and with reference to the draw-

ing which shows:

FIG. 1 a partially sectioned tideview of an electrosurgical radio frequency centing instrument in accordance with the invention in the tip region which
contacts the titsue 16 of a nation. contacts the tissue 16 of a patient,

FIG. 2 a view of the r.f. cutting instrument of FIG. 1

FIG. 3 a schematic, partially sectioned sideview of a further embodiment of and r.f. cutting instrument in accordance with the invention and shaped like a pin-

FIG. 4 a view similar to FIG. 3 of the same coming 60 instrument after switching over into the position provided for effecting coagulation.

As seen in FIGS. 1 and 2 a thin metal tip is used at the bottom of a cylindrical metal rod 19 as the cutting electrode 12. The cutting electrode 12 projects down- 65 wardly significantly beyond the metal rod 19. The metal rod 19 is concentrically sleeved by an insulating sleeve 18 which consists of a highly best-resistant refractory

ceramic or teston material. A thick-walled metal tube 26 is arranged in narrow contact around the insulating sleeve 18 and can be put together of two half shells as shown in FIG. 2. The metal tube is formed at the lower or front end of the instrument body 13 formed in this way as a semi-spherical head which forms the neutral electrode 11. The design of the neutral electrode 11 with a semi-spherical head has the purpose of ensuring better sliding on the tissue 16 during cutting in the di-rection of the arrow f in FIG. 1.

The metal rod 19, the insulating sleeve 18 and the neutral electrode 11 are axially displaced relative to one another in stepped manner in accordance with FIG. 1 in such a way that the path for leakage current between the metal rod 19 and the neutral electrode 11 is as long or large as possible. Moreover, a distinct intermediate space 27 should be formed between the tissue surface and the front end face of the metal rod 19 when placing the instrument body 13 onto the tissue 16 in accordance with FIG. 1, so that current largely flows starting from

the tip of the cutting electrode 12 into the tissue 16.

The metal tube 26, the insulating sleeve 18 and the metal rod 19 with the cutting electrode 12 together form an arrangement concentric to the axis 17.

The metal rod 19 is connected to the one term an r.f. generator (not shown) and the metal tube 26 to the other pole of the r.f. generator, which has a floating output not coupled to earth.

The manner of operation of the r.f. cutting instrument in accordance with the invention is as follows: The instrument is first of all placed in accordance with FIG.

1 onto the tissue 16 which is to be separated by means of
a cut, with a concave ring-like contact surface 14 being formed between the tissue 16 and the neutral electrode 11 and with a very small farmel-like contact surface 15 being formed between the tip of the cutting electrode 12 and the tissue 16. If the z.f. generator is now switched on then an r.f. current indicated by the current lines 28 flows between the cutting electrode 12 and the neutral

The dimensioning of the cutting electrode 12 and of the neutral electrode 11 is so selected that the contact areas 14, 15 have a ratio of approximately 10:1. If the instrument body 13 is now moved in the direction of the arrow f at a speed of approximately 3 cm/sec. over the tissue then a clean cut corresponding to the depth of penetration of the cutting electrode 12 will be formed in the tissue 16 without overheating or even adhesion

accordance with the invention, to axially displace either the metal rod 19 within the insulating sleeve 18 cs, at 45 assumed in FIG. 1, the insulating sleeve 18 within the prepal rules 24 and to calculate a second rules 24 and to calculate an accordance in the prepal rules 24 and to calculate a second rules 24 and to calculate a second rules 25 and to calculate a second rule 25 and to calculate a second rules 25 and to calculate a second rule 25 and to calculate a sec mens rube 26, and to select a predetermined axial pos-tion relative to the metal tube 26 by an adjustment mechanism 29. The adjustment mechanism can for example consist of an adjustment put 30 provided with a circular actuation disk which is arranged concentrically thereto, and of a threaded rod 31 which is connec with the insulating sloeve 18 for the transmission of axial forces. If the nut 30 is axially fixed to the metal tube 26, as indicated in FIG. 1, then really insulating sleeve 18 will be axially displaced relative to the metal tabe 26 on rotation of the aut 30, which leads to a greater or lesser degree of projection of the cutting electrode 12 beyond the neutral electrode 11. The operator can thus prede-

termine the cutting depth with which he wants to operate. This possibility of adjustment is particularly important because for certain electric operations the danger exists that on cutting too deeply into the tissue layers other organs will be unintentionally injured. By select- 5 ing particularly shallow depths of cut using the adjustment mechanism of the invention such injuries can be completely avoided without particular attention being required by the surgeon during electric cutting.

As seen in FIGS. 3 and 4 the neutral electrode 11 10 which surrounds the cutting electrode 12 on both sides is formed by the tip regions of the two limbs 21, 22 of a pincette 13', with the two limbs being mounted in the

upper region on an insulating cap 32.

the cutting electrode 12 is axially displaceably arranged within the insulating cap 32 in a manner not shown in such a way that it is either approximately flush with the neutral electrode 11 in the position of FIG. 3, with the cutting electrode 12 projecting axially forwardly in 20 similar manner to that shown in FIG. 1, or lies clearly behind the ends of the limbs as shown in FIG. 4, so that the pincette 32 can also be used as a normal clamping

dence with FIG. 3 a cf. cutting instrument in accordance with the invention is created in which the two limbs 21, 22 can be pressed from both sides against the insulating sleeve 18 by finger pressure.

A coil 33 with two windings L1 and L2 is built into 30 the insulating cap 32. The one terminal of the winding L2 is connected with the earthed terminal 25 of the r.f. generator 20. The other terminal of the winding I which simultaneously produces the connection to the winding L1 is connected, in accordance with FIG. 4 to 35 one contact of a closing switch 2 which forms one ele-ment of a multiple switch 23 actuated by displacement of the insulating sleeve 18. The other terminal of the winding L1 is connected with the one contact of the first normally open switch I (FIG. 4) and with the one contact of a further switch 4 of the multiple switch 23.

It should be pointed out that, for the sake of clarity, aly those line connections are shown in FIGS. 3 and 4 which are necessary for the operation of the relevant switch position. In actual fact the electrical line connections which can be seen by jointly viewing FIGS. 3 and 4 are present between the various componen

The multiple switch 23 has in total eight fixed contact pairs and five displacement contacts which are located between the contact pairs on the insulating alceve 18, 50 which form the individual switches 1 to 8.

The other (left hand) contact of the individual switch I is connected with the hot terminal 24 of the r.f. generator 20. The other contact of the switch 2 is electrically conductively connected with the other contact of the 55 switch 5 and also with the limb 21. The switch 3 is connected on the one side with the earthed terminal 25 of the s.f. generator 20 and on the other side with the limb 22 of the pincetta 13'. The contacts of the switch 4 are connected to the one contact of the switch 1 and to 60 the one contact of the hand switch 34. The contacts of the switch 5 are connected to the other contact of the hand switch 34 and to the other contact of the switch 2 and to the limb 21 respectively. The contacts of the switch 6 are connected to the cutting electrode 12 and 65 to the one contact of the switch 8 and to the hot terminal 24 of the r.L generator 20 respectively. The contacts of the switch 7 are connected to the earthed terminal 25

of the r.f. generator 20 and to the limb 21 respectively. The contacts of the switch 8 are connected with the one contact of the switch 5 and with the mentioned second contact of the hand switch 34 respectively.

The hand switch 34 serves to switch on the r.f. generator 20

In the cutting position of FIG. 3 the full high frequency voltage is applied between the cutting electrode 12 and the neutral electrode 11 formed by the tip regions of the limbs 21, 22. The current flow from the r.f. generator 20 takes place via the poles 24, 25 in the manper shown in FIG. 3.

In accordance with the invention a low frequency control current with a low voltage is superimposed on The insulating sleeve containing the metal rod 19 and 15 the r.f. current. If the hand switch 34 is closed then this low frequency control current flows via the windings of the coil 33 which acts as an r.f. filter and further r.f. coupling coils 35 to a schematically illustrated switching relay 36 in the r.f. generator 20 which switches on the r.f. generator 20 when it engages. Thus, the r.f. generator 20 can be set in operation by closing the hand euritch 34

While the sliding contacts on the insulating sleeve 18 only close the switches 6, 7 and 8 in the cutting position When the insulating sleeve 18 is advanced in accor- 25 of FIG. 3 these three switches are open in the congulating position of FIG. 4 and in their place the switches 1 to 5 are closed. The insulating sleeve 18 is retracted in this position sufficiently far that the cutting electrode 11, which is here shaped like a needle, cannot come into contact with the tissue.

In the switch position of FIG. 4 the full r.f. voltage of the r.f. generator 20 is applied to the windings of the coil 33. The two limbs 21, 22 of the pincette are fully electrically insulated from one another in this positio and receive a reduced all voltage from the winding 1.2 of the coil 33. The voltage is thus stepped down (trans-

If tissue is now clamped between the tip regions of the limbs 21, 22 and the r.f. generator 20 is agr nected by closing the hand switch 34 then a r.L. current flows through the branches 21, 22 into the tissue and there generates the electrical heat losses accessary for

In the switch position of FIG. 4 a low freque e- 45 control current for the switch-in relay 36 which is su-ad perimposed on the LL current also flows via the winding Li of the coil 33 with Li forming an element of a

cent circuit.

The load impedance for the cutting of FIG. 3 and for the congulation of FIG. 4 is different. Whereas one can reckon with a load impedance of ca. 1000 Ohms during cutting the load impedance during congulation amounts to approximately 50 to 100 Ohms. In order to obtain troublefree functioning in the various switch positions the output oscillating circuit of the r.f. generator 20 must be matched to these conditions respectively.

A particular advantage of the embodiment of FIGS. 3 and 4 lies in the fact that in the position of use for the cutting process the characteristic of the t.I. generator required for this application can be brought into effect, namely that the power increases with increasing resistance. In the position of use for coagulation in accor-dance with FiG. 4 a power characteristic results. brought about by the winding L2 of the coil 33, such that the power drops off with increasing resistance.

The r.L generator 20 can also have an output decoupled from earth (floating output) with terminal 25 then no longer being connected to earth as shown in FIG. 3.

One of the essential advantages of the bipolar application technique of the invention is the reduced flow of leakage currents to earthed parts of the operating table which has been reduced to a non-dangerous minimum by the freedom of the patient current circuit from earthing and ground leaks.

I daine

1. An electro-surgical apparatus for connecting to first and second outputs of an electrical generator com- 10 pridag:

a first electrode comprising first and second generally clongate members, the members being spaced apart at one end and being displaceable relative to each other at the other end;

a second electrode disposed between the first and second members of the first electrode and beign generally parallel thereto: ..

means for displacing the second electrode relative to 20 the first electrode;

means for connecting the first output of the electrical generator to the first and second members of the first electrode and for connecting the second output of the electrical generator to the second elec- 25 trode when the second electrode is displaced to a first position relative to the first electrode; and

means for alternately connecting the first output of the electrical generator to the first member of the first electrode and for connecting the second output of the electrical generator to the second mem-ber of the first electrode when the second electrode is displaced to a second position relative to the first electrode.

2. The apparatus according to claim 1 further com**buspat**

means for electrically insulating the members of the first electrode from each other, and

means for connecting the first output of the electrical generator to the first member of the first electrode and for consecting the second output of the electrical generator to the second member of the first clectrose.

3. The apparatus according to claim 1 further com-

prising:

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means for applying a first voltage to the first and second electrodes when the second electrode is displaced to the first position relative to the first electrode; and

means for applying a second voltage to the first and second members of the first electrode when the second electrode is displaced to the second position

relative to the first electrode.

A 23664

United States Patent [19]

[11] Patent Number:

4,706,667

Roos

[45] Date of Patent:

Nov. 17, 1987

[54]	ELECTRO CUTTING	SURGICAL HIGH FREQUENCY INSTRUMENT
[75]	Inventor:	Eberhard Roos, Tuttlingen, Fed. Rep. of Germany
[73]	Assignee:	Berchtold Medizin-Elektronik GmbH & Co., Tuttlingen, Fed. Rep. of Germany
[21]	Appl. No.:	892,883
[22]	Filed:	Jul. 28, 1986
	Rela	ted U.S. Application Data
[62]	Division of	Ser. No. 747,086, Jun. 20, 1985.
[30]	Foreig	n Application Priority Data
Jur	ı. 25, 1984 [C	E] Fed. Rep. of Germany 3423356
[51] [52] [58]	U.S. Cl	A61B 17/36 128/303.14; 128/303.17 arch
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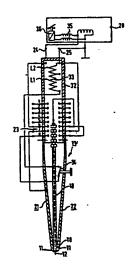
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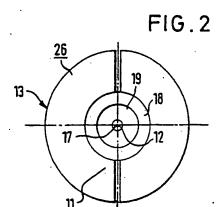
Primary Examiner—William E. Kamm Assistant Examiner—Max F. Hindenburg Attorney, Agent, or Firm—Townsend and Townsend

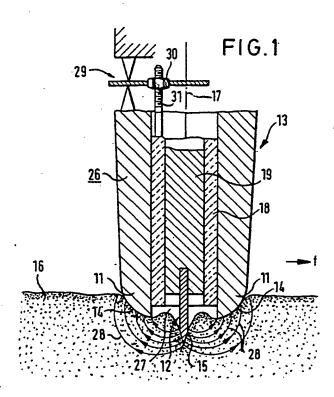
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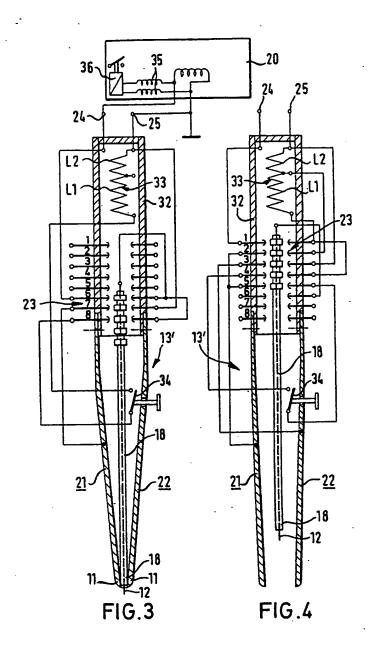
In an electro-surgical r.f. cutting instrument in which the neutral electrode (11) is arranged on both sides of the cutting electrode (12) but is however set back relative to the cutting electrode (12) on the instrument body (13). The ratio of the sizes of the contact areas (14, 15) of the neutral electrode (11) and of the cutting electrode (12) is greater than 7:1 and smaller than 20:1.

3 Claims, 4 Drawing Figures









ELECTRO SURGICAL HIGH FREQUENCY CUTTING INSTRUMENT

This is a division of application Ser. No. 747,086, filed 5 June 20, 1985.

The invention relates to an electro-surgical high frequency cutting instrument comprising a preferably elongate instrument body from which, in the operative state, a small area cutting electrode projects forwardly, 10 and a large area neutral electrode which can be brought into contact with the patient near to the cutting electrode.

In a known electro-surgical high frequency cutting instrument of this kind (DE-OS No. 25 21 719) the 15 neutral electrode is admittedly arranged in the immediate vicinity of the cutting electrode, it is however so separated from the tissue by a plastic cover, or by its arrangement in an endoscope, that it can only enter into electrical contact with the cutting electrode electrolyti- 20 cally via the secretion which is present during the cutting process. As a result, it is difficult to maintain the current intensity required for troublefree cutting in a required precisely defined manner at the cutting electrode. Thus, if the power setting at the r.f. generator is 25 too high, burns can result or, if the power setting is too low, then a poor cut or indeed injury occurs because the tissue to be cut sticks to the cutting electrode as a result of coagulation processes.

The principal object of the invention is to provide an 30 electro-surgical high frequency cutting instrument of the initially named kind in which current conditions which are largely precisely defined are present at the cutting electrode during the making of a cut substantially perpendicular to the longitudinal axis of the body 35 of the instrument, with the current conditions ensuring a troublefree clean cut of the tissue without overheating of the tissue and without the tissue and the instrument sticking together.

In order to satisfy this object the invention provides 40 that the neutral electrode is arranged on the instrument body on both sides of the cutting electrode, but set back relative to the cutting electrode, in such a way that it is supported on the tissue on both sides of the cutting electrode while the axially projecting cutting electrode 45 penetrates into the tissue; and that the ratio of the sizes of the contact surfaces between the neutral electrode and the tissue on the one hand and between the cutting electrode and the tissue on the other hand, is greater than 7:1.

If, in a cutting instrument of this kind, a power of for example 5 to 10 Watts per mm² is applied to the cutting electrode then a power density occurs at the cutting electrode, which is preferably formed as a point, which is such that the heat necessary for tissue separation is 55 generated in the tissue and in the tissue cells. The fact that the neutral electrode itself is likewise in current conducting contact with the tissue ensures a problemfree flow of current between the cutting electrode and the neutral electrode. In other words the transition 60 resistance between the two electrodes is substantially constant. As a result of the larger area of the neutral electrode which is in contact with the tissue the power density at the neutral electrode is reduced so far that with normal cutting speeds of the order of several cm 65 per sec. not even tissue heating, which could lead to coagulation, occurs. The neutral electrode thus slides smoothly over the tissue during cutting while the cut-

ting electrode, which is arranged directly alongside or between it, causes the required strong heating at the desired location of the cut that is necessary to execute a smooth cut. As the resistance between the cutting electrode and neutral electrode is largely constant the high frequency power of the generator can be regulated to a value at which overheating of the tissue is also effectively avoided in the area of the cutting electrode, but such that a clean cut is nevertheless obtained.

The radiofrequency cutting instrument of the invention is uncritical in its operation by the surgeon because a problem-free electric cut is effected through the cutting electrode even with irregular cutting speed, without tissue damage or adhesion occurring in the region of the neutral electrode.

In order to prevent the cutting instrument of the invention from becoming awkward to handle provision should further be made that the ratio of the sizes of the contact areas of the neutral electrode and of the cutting electrode is smaller than 20:1 and preferably smaller than 15:1.

One obtains particularly good electro-surgical cutting characteristics combined with a compact and slim construction of the instrument body if the ratio of the sizes of the contact surfaces of the neutral electrode and of the cutting electrode is approximately 10:1.

Although the cutting electrode could also have the form of a narrow blade, it is preferred for the cutting electrode to project substantially axially and preferably also in a straight line from the tip of the instrument body. If the cutting electrode is in addition formed with a sharp tip then the power density in the tip region is particularly large which is important for a smooth cut free of injury.

The depth of cut preferably amounts to 0.5 to 5 mm. The extent of the neutral electrode which surrounds the cutting electrode in the direction perpendicular to the axis of the instrument body preferably amounts from 2 to 6, in particular from 3 to 5 and most particularly to approximately 4 mm.

The cutting speed conveniently amounts to from 1 to 5, in particular from 2 to 4 and preferably to approximately 3 cm/sec.

The distance of the cutting electrode from the neutral electrode in the direction perpendicular to the axis of the instrument body usefully amounts to from 5 to 15 and in particular to approximately 10 mm.

When the cutting electrode has a needle-like up this tip preferably has a diameter from 0.1 to 0.5, in particular of from 0.2 to 0.4 and particularly of approximately 0.3 mm. The cutting electrode preferably projects axially beyond the neutral electrode by from 1 to 5 mm.

The tip of the cutting electrode can usefully have a length from 2 to 5 mm and preferably of approximately 3 mm.

As electrical insulation is necessary between the two electrodes a preferred practical embodiment is usefully arranged in such a way that the cutting electrode projects axially from an insulating body arranged inside the neutral electrode.

In order to increase the path for leakage currents between the two electrodes an advantageous further embodiment of the invention is characterised in that the insulating body is set back axially relative to the contact surface of the neutral electrode.

Furthermore, a practical realisation of the invention provides that the insulating body is formed as an insulating sleeve in which a metal rod is located which is

With this arrangement it is also expedient if the metal rod is set back axially relative to the neutral electrode, and preferably also relative to the insulating sleeve, in 5 order to further reduce losses by leakage currents directly between the two electrodes.

It is of particular advantage if the cutting electrode is axially displaceably arranged on the instrument body. In this way the depth of cut can be preselected by the 10 rection of the arrow f in FIG. 1. operator before performing an electric cut, with the range of adjustment being advantageously selectable between 0.5 and 5 mm.

In one realisation of the invention the neutral electrode can be circular cross-section and can concentri- 15 cally surround the cutting electrode. In this case the instrument thus has approximately the shape of a pencil or stylus which can also be correspondingly held and guided by the operator. The metal tip which forms the cutting electrode projects from the bottom of the stylus 20 at the center.

A further embodiment is constructed so that the neutral electrode is realised by the tips of the two limbs of a pincette or pair of tweezers which forms the insulating body. With this arrangement it is particularly expedient 25 if the insulating sleeve with the cutting electrode can be retracted relative to the limbs of the pincette. In this manner the pincette can also be used without the cutting electrode of the invention.

Finally, this embodiment can be so further developed 30 that the two branches of the pincette are insulated from one another, with a switch being provided which, when the cutting electrode and the insulating sleeve are retracted connects the limbs to the two voltage bearing terminals of the r.f. generator.

As a result of this construction the cutting instrument can also be used for coagulation, it being necessary to take appropriate electrical matching measures at the r.f. generator.

In order to ensure injury-free sliding of the neutral 40 electrode 11. electrode on the tissue surface during the cut the contact surface of the neutral electrode should be of appropriate smooth and rounded shape. In particular, the neutral electrode is made of substantially hemispherical rounded shape at its end which enters into 45 contact with the tissue.

The invention will now be described in the following by way of example only and with reference to the drawing which shows:

FIG. 1 a partially sectioned sideview of an electro- 50 surgical radio frequency cutting instrument in accordance with the invention in the tip region which contacts the tissue 16 of a patient,

FIG. 2 a view of the r.f. cutting instrument of FIG. 1 from below.

FIG. 3 a schematic, partially sectioned sideview of a further embodiment of and r.f. cutting instrument in accordance with the invention and shaped like a pincette, and

FIG. 4 a view similar to FIG. 3 of the same cutting 60 instrument after switching over into the position provided for effecting coagulation.

As seen in FIGS. 1 and 2 a thin metal tip is used at the bottom of a cylindrical metal rod 19 as the cutting electrode 12. The cutting electrode 12 projects down-65 wardly significantly beyond the metal rod 19. The metal rod 19 is concentrically sleeved by an insulating sleeve 18 which consists of a highly heat-resistant refractory

ceramic or teflon material. A thick-walled metal tube 26 is arranged in narrow contact around the insulating sleeve 18 and can be put together of two half shells as shown in FIG. 2. The metal tube is formed at the lower or front end of the instrument body 13 formed in this way as a semi-spherical head which forms the neutral electrode 11. The design of the neutral electrode 11

with a semi-spherical head has the purpose of ensuring better sliding on the tissue 16 during cutting in the di-

The metal rod 19, the insulating sleeve 18 and the neutral electrode 11 are axially displaced relative to one another in stepped manner in accordance with FIG. 1 in such a way that the path for leakage current between the metal rod 19 and the neutral electrode 11 is as long or large as possible. Moreover, a distinct intermediate space 27 should be formed between the tissue surface and the front end face of the metal rod 19 when placing the instrument body 13 onto the tissue 16 in accordance with FIG. 1, so that current largely flows starting from the tip of the cutting electrode 12 into the tissue 16.

The metal tube 26, the insulating sleeve 18 and the metal rod 19 with the cutting electrode 12 together form an arrangement concentric to the axis 17.

The metal rod 19 is connected to the one terminal of an r.f. generator (not shown) and the metal tube 26 to the other pole of the r.f. generator, which has a floating output not coupled to earth.

The manner of operation of the r.f. cutting instrument in accordance with the invention is as follows: The instrument is first of all placed in accordance with FIG. 1 onto the tissue 16 which is to be separated by means of a cut, with a concave ring-like contact surface 14 being formed between the tissue 16 and the neutral electrode 35 11 and with a very small funnel-like contact surface 15 being formed between the tip of the cutting electrode 12 and the tissue 16. If the r.f. generator is now switched on then an r.f. current indicated by the current lines 28 flows between the cutting electrode 12 and the neutral

The dimensioning of the cutting electrode 12 and of the neutral electrode 11 is so selected that the contact areas 14, 15 have a ratio of approximately 10:1. If the instrument body 13 is now moved in the direction of the arrow f at a speed of approximately 3 cm/sec. over the tissue then a clean cut corresponding to the depth of penetration of the cutting electrode 12 will be formed in the tissue 16 without overheating or even adhesion occurring at the contact surface, because the current density close to the cutting electrode 12 is very high but rapidly reduces at a distance therefrom.

In order to adjust the depth of cut it is possible, in accordance with the invention, to axially displace either the metal rod 19 within the insulating sleeve 18 or, as assumed in FIG. 1, the insulating sleeve 18 within the metal tube 26, and to select a predetermined axial position relative to the metal tube 26 by an adjustment mechanism 29. The adjustment mechanism can for example consist of an adjustment nut 30 provided with a circular actuation disk which is arranged concentrically thereto, and of a threaded rod 31 which is connected with the insulating sleeve 18 for the transmission of axial forces. If the nut 30 is axially fixed to the metal tube 26, as indicated in FIG. 1, then really insulating sleeve 18 will be axially displaced relative to the metal tube 26 on rotation of the nut 30, which leads to a greater or lesser degree of projection of the cutting electrode 12 beyond the neutral electrode 11. The operator can thus prede-

termine the cutting depth with which he wants to operate. This possibility of adjustment is particularly important because for certain electric operations the danger exists that on cutting too deeply into the tissue layers other organs will be unintentionally injured. By select- 5 ing particularly shallow depths of cut using the adjustment mechanism of the invention such injuries can be completely avoided without particular attention being required by the surgeon during electric cutting.

which surrounds the cutting electrode 12 on both sides is formed by the tip regions of the two limbs 21, 22 of a pincette 13', with the two limbs being mounted in the upper region on an insulating cap 32.

the cutting electrode 12 is axially displaceably arranged within the insulating cap 32 in a manner not shown in such a way that it is either approximately flush with the neutral electrode 11 in the position of FIG. 3, with the cutting electrode 12 projecting axially forwardly in 20 the r.f. generator 20 when it engages. Thus, the r.f. similar manner to that shown in FIG. 1, or lies clearly behind the ends of the limbs as shown in FIG. 4, so that the pincette 32 can also be used as a normal clamping

When the insulating sleeve 18 is advanced in accor- 25 dance with FIG. 3 a r.f. cutting instrument in accordance with the invention is created in which the two limbs 21, 22 can be pressed from both sides against the insulating sleeve 18 by finger pressure.

A coil 33 with two windings L1 and L2 is built into 30 the insulating cap 32. The one terminal of the winding L2 is connected with the earthed terminal 25 of the r.f. generator 20. The other terminal of the winding L2, which simultaneously produces the connection to the winding L1 is connected, in accordance with FIG. 4, to 35 one contact of a closing switch 2 which forms one element of a multiple switch 23 actuated by displacement of the insulating sleeve 18. The other terminal of the winding L1 is connected with the one contact of the contact of a further switch 4 of the multiple switch 23.

It should be pointed out that, for the sake of clarity, only those line connections are shown in FIGS. 3 and 4 which are necessary for the operation of the relevant tions which can be seen by jointly viewing FIGS. 3 and 4 are present between the various components.

The multiple switch 23 has in total eight fixed contact pairs and five displacement contacts which are located which form the individual switches 1 to 8.

The other (left hand) contact of the individual switch 1 is connected with the hot terminal 24 of the r.f. generator 20. The other contact of the switch 2 is electrically conductively connected with the other contact of the 55 switch 5 and also with the limb 21. The switch 3 is connected on the one side with the earthed terminal 25 of the r.f. generator 20 and on the other side with the limb 22 of the pincetta 13'. The contacts of the switch 4 the one contact of the hand switch 34. The contacts of the switch 5 are connected to the other contact of the hand switch 34 and to the other contact of the switch 2 and to the limb 21 respectively. The contacts of the switch 6 are connected to the cutting electrode 12 and 65 to the one contact of the switch 8 and to the hot terminal 24 of the r.f. generator 20 respectively. The contacts of the switch 7 are connected to the earthed terminal 25

of the r.f. generator 20 and to the limb 21 respectively. The contacts of the switch 8 are connected with the one contact of the switch 5 and with the mentioned second contact of the hand switch 34 respectively.

The hand switch 34 serves to switch on the r.f. gener-

In the cutting position of FIG. 3 the full high frequency voltage is applied between the cutting electrode 12 and the neutral electrode 11 formed by the tip re-As seen in FIGS. 3 and 4 the neutral electrode 11 10 gions of the limbs 21, 22. The current flow from the r.f. generator 20 takes place via the poles 24, 25 in the manner shown in FIG. 3.

In accordance with the invention a low frequency control current with a low voltage is superimposed on The insulating sleeve containing the metal rod 19 and 15 the r.f. current. If the hand switch 34 is closed then this low frequency control current flows via the windings of the coil 33 which acts as an r.f. filter and further r.f. coupling coils 35 to a schematically illustrated switching relay 36 in the r.f. generator 20 which switches on generator 20 can be set in operation by closing the hand

> While the sliding contacts on the insulating sleeve 18 only close the switches 6, 7 and 8 in the cutting position of FIG. 3 these three switches are open in the coagulating position of FIG. 4 and in their place the switches 1 to 5 are closed. The insulating sleeve 18 is retracted in this position sufficiently far that the cutting electrode 11, which is here shaped like a needle, cannot come into contact with the tissue.

> In the switch position of FIG. 4 the full r.f. voltage of the r.f. generator 20 is applied to the windings of the coil 33. The two limbs 21, 22 of the pincette are fully electrically insulated from one another in this position and receive a reduced r.f. voltage from the winding L2 of the coil 33. The voltage is thus stepped down (transformed).

If tissue is now clamped between the tip regions of the limbs 21, 22 and the r.f. generator 20 is again confirst normally open switch 1 (FIG. 4) and with the one 40 nected by closing the hand switch 34 then a r.f. current flows through the branches 21, 22 into the tissue and there generates the electrical heat losses necessary for coagulation.

In the switch position of FIG. 4 a low frequency switch position. In actual fact the electrical line connec- 45 control current for the switch-in relay 36 which is superimposed on the r.f. current also flows via the winding L1 of the coil 33 with L1 forming an element of a resonant circuit.

The load impedance for the cutting of FIG. 3 and for between the contact pairs on the insulating sleeve 18, 50 the coagulation of FIG. 4 is different. Whereas one can reckon with a load impedance of ca. 1000 Ohms during cutting the load impedance during coagulation amounts to approximately 50 to 100 Ohms. In order to obtain troublefree functioning in the various switch positions the output oscillating circuit of the r.f. generator 20 must be matched to these conditions respectively.

A particular advantage of the embodiment of FIGS. 3 and 4 lies in the fact that in the position of use for the cutting process the characteristic of the r.f. generator are connected to the one contact of the switch 1 and to 60 required for this application can be brought into effect, namely that the power increases with increasing resistance. In the position of use for coagulation in accordance with FIG. 4 a power characteristic results, brought about by the winding L2 of the coil 33, such that the power drops off with increasing resistance.

The r.f. generator 20 can also have an output decoupled from earth (floating output) with terminal 25 then no longer being connected to earth as shown in FIG. 3. One of the essential advantages of the bipolar application technique of the invention is the reduced flow of leakage currents to earthed parts of the operating table which has been reduced to a non-dangerous minimum by the freedom of the patient current circuit from earthing and ground leaks.

I claim:

- 1. An electro-surgical apparatus for connecting to first and second outputs of an electrical generator comprising:
 - a first electrode comprising first and second generally elongate members, the members being spaced apart at one end and being displaceable relative to each other at the other end;
 - a second electrode disposed between the first and second members of the first electrode and beign generally parallel thereto;
 - means for displacing the second electrode relative to the first electrode;
 - means for connecting the first output of the electrical generator to the first and second members of the first electrode and for connecting the second output of the electrical generator to the second electrode when the second electrode is displaced to a first position relative to the first electrode; and

means for alternately connecting the first output of the electrical generator to the first member of the first electrode and for connecting the second output of the electrical generator to the second member of the first electrode when the second electrode is displaced to a second position relative to the first electrode.

2. The apparatus according to claim 1 further comprising:

means for electrically insulating the members of the first electrode from each other; and

- means for connecting the first output of the electrical generator to the first member of the first electrode and for connecting the second output of the electrical generator to the second member of the first electrode.
- 3. The apparatus according to claim 1 further comprising:
- means for applying a first voltage to the first and second electrodes when the second electrode is displaced to the first position relative to the first electrode; and
- means for applying a second voltage to the first and second members of the first electrode when the second electrode is displaced to the second position relative to the first electrode.

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IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

2004 JUL -8 PH 3: 44

ARTHROCARE CORPORATION,

Plaintiff,

SMITH & NEPHEW, INC.

C.A. No. 01-504-SLR

Defendant.

SMITH & NEPHEW, INC.,

Counterclaim Plaintiff,

ARTHROCARE CORPORATION, AND ETHICON, INC.,

Counterclaim Defendants.

SMITH & NEPHEW'S SECOND NOTICE OF APPEAL

PLEASE TAKE NOTICE that Smith & Nephew, Inc. ("Smith & Nephew"), defendant and counterclaim-plaintiff in the above-captioned case, hereby appeals to the United States Court of Appeals for the Federal Circuit from:

- (1) the Order, dated June 9, 2004, and the Amended Order, dated June 24, 2004, enjoining Smith & Nephew from infringing, contributing to the infringement of, and/or inducing the infringement of the patents-in-suit, and ordering Smith & Nephew to take certain actions (D.L 522, 524);
- (2) the Order and Memorandum Opinion, dated April 27, 2004, and the Revised Order, dated April 28, 2004, denying Smith & Nephew's motion for reconsideration of orders granting ArthroCare Corp.'s ("ArthroCare") motion for

permanent injunction and denying Smith & Nephew's motion to stay the injunction pending appeal (D.I. 507, 508, and 509);

- (3) the Revised Order, dated April 27, 2004, dismissing Smith & Nephew's antitrust counterclaim and granting ArthroCare's motion to dismiss that counterclaim (D.I. 506);
- (4) the Order, dated April 8, 2004, denying Smith & Nephew's unopposed motion to lift the stay to oppose ArthroCare's motion to dismiss the antitrust counterclaim (D.I. 499);
- (5) the Orders and Memorandum Opinions, dated March 10, 2004, denying Smith & Nephew's motion for judgment as a matter of law pursuant to Fed. R. Civ. P. 50(b), denying Smith & Nephew's motion for a new trial, denying Smith & Nephew's cross motion to strike motion for entry of judgment of no inequitable conduct, granting ArthroCare's motion for entry of judgment of no inequitable conduct, granting ArthroCare's motion for permanent injunction, and granting ArthroCare's motion to dismiss Smith & Nephew's antitrust counterclaim (D.I. 481, 482, 483, 484);
- (6) the Judgment for ArthroCare against Smith & Nephew, dated June 20, 2003 (D.I. 452);
- (7) those portions of the Memorandum Order, dated April 9, 2003, construing the disputed claim language in U.S. Patents '536, '882 and '592 in a manner that differed from that proposed by Smith & Nephew (D.I. 353); and
- (8) each and every order, opinion, ruling, finding and/or conclusion of the District Court which produced or is subsumed within those portions of such Judgment, Orders, Memorandum Opinions and/or Memorandum Order, and/or was adverse to Smith & Nephew.

Enclosed herewith is a \$250 docketing fee required by 28 U.S.C. § 1913 and the \$5 filing fee required by 28 U.S.C. §1917.

Dated: July 8, 2004

FISH & RICHARDSON P.C.

By:

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Attorneys for Defendant, Counterclaim-Plaintiff, SMITH & NEPHEW, INC.

CERTIFICATE OF SERVICE

I hereby certify that on this 8th day of July, 2004, a true and correct copy of the foregoing SMITH & NEPHEW'S SECOND NOTICE OF APPEAL was caused to be served on the attorneys of record at the following addresses as indicated:

BY HAND
Jack B. Blumenfeld, Esq.
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Attorney for Plaintiff/Counterclaim-Defendant ArthroCare Corporation

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BY HAND Steven J. Balick, Esq. Ashby & Geddes 222 Delaware Avenue, 17th Floor P. O. Box 1150 Wilmington, DE 19899 Attorney for Counterclaim-Defendant Ethicon, Inc.

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June 8, 2004

BY HAND

The Honorable Sue L. Robinson United States District Court 844 King Street Wilmington, DE 19801

Re:

ArthroCare v. Smith & Nephew C.A. No. 01-504 (SLR)

Dear Chief Judge Robinson:

Enclosed is a copy of the June 3, 2004 Order of the Federal Circuit, denying Smith & Nephew's motion for a stay of the injunction pending appeal, which Ms. Margolis referred to during the telephone conference this morning.

JBB/bls

cc: Peter T. Dalleo, Clerk (By Hand) William J. Marsden, Jr., Esquire (By Hand) John G. Day, Esquire (By Hand) Jared Bobrow, Esquire (By Fax) Ruffin B. Cordell, Esquire (By Fax) Vicki Margolis, Esquire (By Fax)

NOTE: Pursuant to Fed. Cir. R. 47.6, this order is not citable as precedent. It is a public order.

United States Court of Appeals for the Federal Circuit

04-1323

ARTHROCARE CORPORATION,

Plaintiff/Counterclaim Defendant-Appellee,

and

ETHICON, INC.,

Counterclaim Defendant-Appellee,

V.

SMITH & NEPHEW, INC.,

Defendant/Counterclaimant-Appellant.

ON MOTION

Before NEWMAN, LOURIE, and CLEVENGER, Circuit Judges.
LOURIE, Circuit Judge.

ORDER

Smith & Nephew, Inc. moves for a stay, pending appeal, of the permanent injunction issued by the United States District Court for the District of Delaware. ArthroCare Corporation opposes. Smith & Nephew replies.

ArthroCare sued Smith & Nephew for infringement of three patents relating to electrosurgical devices and methods. The jury returned a verdict of infringement and

rejected Smith & Nephew's assertions of invalidity. Subsequently, the district court granted ArthroCare's motion for entry of a permanent injunction. Smith & Nephew moves for a stay of the injunction, pending disposition of its appeal.

In deciding whether to grant a stay, pending appeal, this court "assesses the movant's chances of success on the merits and weighs the equities as they affect the parties and the public." E. I. du Pont de Nemours & Co. v. Phillips Petroleum Co., 835 F.2d 277, 278 (Fed. Cir. 1987). See also Standard Havens Prods v. Gencor Indus., 897 F.2d 511 (Fed. Cir. 1990). To prevail, a party moving for a stay, pending appeal, must establish a strong likelihood of success on the merits or, failing that, nonetheless demonstrate a substantial case on the merits provided that the harm factors militate in its favor. Hilton v. Braunskill, 481 U.S. 770, 778 (1987).

Smith & Nephew argues that it has established a strong likelihood of success on the merits or, at a minimum, demonstrated a substantial case on the merits on several grounds. For purposes of this motion, we discuss Smith & Nephew's first and primary argument. Smith & Nephew asserts that it was denied due process because the district court did not allow Smith & Nephew to file a response to ArthroCare's motion to dismiss Smith & Nephew's antitrust counterclaims before granting the motion. ArthroCare points out that Smith & Nephew had the opportunity to respond, and did, in the motion for reconsideration, and that the district court considered Smith & Nephew's arguments in that context and found them unavailing. Based on the papers submitted, Smith & Nephew has not met its burden of establishing a strong likelihood of success or a substantial question on that issue or the other issues raised. See Hilton, 481 U.S. at 778. Therefore a stay, pending appeal, is not warranted.

04-1323

Accordingly,

IT IS ORDERED THAT:

The motion is denied.

FOR THE COURT

Alan D. Lourie

Circuit Judge

JUN - 3 2004

Date

cc: Ruffin B. Cordell, Esq.
Jared Bobrow, Esq.
George F. Pappas, Esq.

s16

FILED U.S. COURT OF APPEALS FOR THE FEDERAL CIRCUIT

JUN - 3 2004

JAN HORBALY CLERK

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